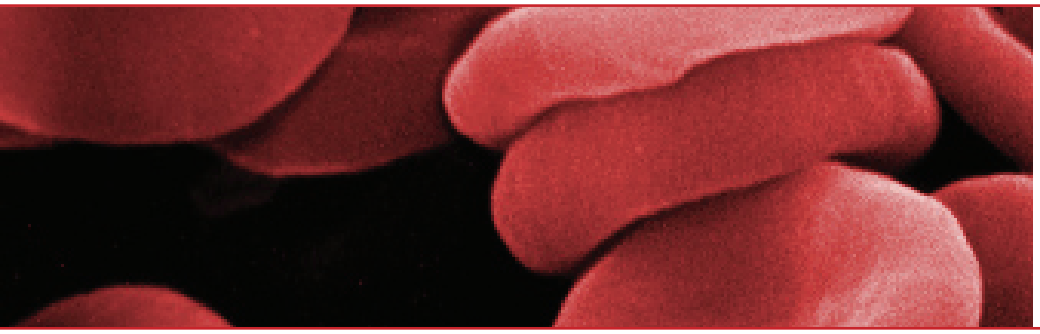
mythic 22 CT



Orphée

User's Manual

Orphée SA

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Cod. M22CT/UM-EN/003

REVISIONS

Revision Nb	Date	Author	Software	Comments
01	23/10/06	HC	> V1.0	Creation
02	11/01/08	HC	> V2.0	English correction, Section 4.2 modified
03	25/05/08	CM/HC	> V2.2.0	Update of the prompts

CONTACT ADDRESS

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LOCAL AGENT

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READ THIS BEFORE USING THE EQUIPMENT

	WARNING ! RISK OF DANGER ! Indicates a procedure to be strictly respected in order to avoid any risks for the operator (user) or damages on the instrument or on the quality of results.
	Indicates that wearing gloves is mandatory before performing the described operation due to risk of contact with materials that may be infectious.
	Indicates hot temperatures surfaces and risk of burns
NOTA	**Indicates important additional information**

DANGER

Misuse of electrical equipment may cause electrocution, burns, fire and others hazards.

⇨ Check that the voltage setting matches the supply voltage.
⇨ Protective grounding is required, plug the **MYTHIC 22 CT** into a supply outlet which has an earth connection.
⇨ Preserve a good access to the supply outlet to be able to unplug the **MYTHIC 22 CT** in emergency case.
⇨ Do not place the power supply adapter in liquid, nor put it where it could fall into liquid. If the power supply adapter becomes wet, unplug it before touching it.
⇨ Do not use the **MYTHIC 22 CT** if it is not working properly, or if it has suffered any damage (damage to the supply cord or its plug; damage caused by dropping the power supply adapter).
⇨ Do not let the power supply adapter or its flexible cord coming in contact with surfaces which are too hot to touch.
⇨ Do not place anything on top of the **MYTHIC 22 CT**
⇨ Do not use the **MYTHIC 22 CT** where aerosol sprays are being used, or where oxygen is being administered.
⇨ Do not use the **MYTHIC 22 CT** outside.
⇨ Always switch off the **MYTHIC 22 CT** and disconnect the power adaptor before dismantling any part.

⇨ The **MYTHIC 22 CT** is an automated hematology analyzer for in vitro diagnostic to be used in clinical laboratories by an authorized people.

- Only human blood or artificial control blood should be run.
- Only the reagents mentioned in this manual are permitted to be used.
- The optimum performances can be only achieved if the cleaning and maintenance procedures are carefully followed.

⇨ Due to the use of this equipment, all parts and surfaces of the **MYTHIC 22 CT** are potentially infective. Wearing rubber gloves is highly recommended and after completion of work, wash hands with disinfectant.
⇨ Always replace or use parts of the equipment supplied by ORPHEE's representative.
⇨ Basic safety precautions should always be taken. If the equipment is not used according to the manufacturer's instructions, the protective by the equipment may be impaired.
⇨ The treatment of waste and the elimination of a part or the complete instrument must be done in compliance with the local legislation.
⇨ Any output or input connections (except the printer and the barcode reader supplied by ORPHEE) cannot be done without the ORPHEE representative authorization.
⇨ Do not open the door located on the right side of the instrument (see section 1.1.3) when a fluidic cycle is in progress for it would lead to an immediate stop. To re-start, shut the door and run a Control cycle (see section 9.3.1)

KEEP THESE INSTRUCTIONS

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This equipment needs special precautions regarding general requirements for safety.

Guidance and manufacturer's declaration – Electromagnetic emissions		
The MYTHIC 22 CT is intended for use in the electromagnetic environment specified below. The customer or the user of the MYTHIC 22 CT should assure that it is used in such an environment.		
Emissions test	**Compliance level**	**Electromagnetic environment - guidance**
Harmonic emissions IEC 61000-3-2	Class A	The MYTHIC 22 CT is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – Electromagnetic immunity			
The MYTHIC 22 CT is intended for use in the electromagnetic environment specified below. The customer or the user of the MYTHIC 22 CT should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT* (>95 % dip in *UT*) for 5 sec	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MYTHIC 22 CT requires continued operation during power mains interruptions, it is recommended that the MYTHIC 22 CT be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *UT* is the a.c. mains voltage prior to application of the test level.			

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Guidance and manufacturer's declaration – Electromagnetic immunity			
The MYTHIC 22 CT is intended for use in the electromagnetic environment specified below. The customer or the user of the MYTHIC 22 CT should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the MYTHIC 22 CT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150Khz to 80Mhz	3 Vrms	$d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 Vrms 80Mhz to 2,5Ghz	3 Vrms	$d = 1,2\sqrt{P}$ 80MHz to 800MHz $d = 2,3\sqrt{P}$ 800MHz to 2,5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80Mhz and 800MHz, the higher frequency range applies. NOTE 2 Theses guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM an FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should considered. If the measured field strength in the location in which the MYTHIC 22 CT is used exceeds the applicable RF compliance level above, the MYTHIC 22 CT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MYTHIC 22 CT.

[b] Over the frequency range 150KHz to 80MHz, field strengths should be less than 3V/m.

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NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The user may find the following booklet, prepared by the Federal Communications Commission, helpful:
How to identify and Resolve Radio/TV Interference Problems. This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402, Stock No. 004-000-00345-4.
Pursuant to Part 15.21 of the FCC Rules, any changes or modifications to this equipment not expressly approved by C2

The symbol on the product indicates that this product may not be treated as household waste. Instead it shall be handed over the applicable collection point for the recycling of electrical and electronic equipment. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. For more detailed information about recycling of this product, please contact your local city office or your distributor of this product.

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KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITA

Name und Adresse der Firma
Nom et adresse de l'entreprise
Nome e indirizzo della ditta
Name and address of the firm

Orphée S.A.
19 Chemin du Champ des Filles
1228 Plan Les Ouates

Wir erklären in alleiniger Verantwortung, dass
Nous déclarons sous notre propre responsabilité que
Dichiariamo sotto nostra responsabilità che
We declare under our sole responsibility that

das Medizinprodukt für die In-vitro-Diagnostik
le dispositif médical de diagnostic in vitro
il dispositivo medico-diagnostico in vitro
the in vitro diagnostic medical device

Mythic 22 CT
Ref. M22CT

mit folgender Klassifizierung nach der Richtlinie über In-vitro-Diagnostika 98/79/EG
avec la classification selon la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE
con la classificazione secondo la direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE
classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC

☐ Produkt der Liste A, Anhang II / Dispositif de la liste A, annexe II / Dispositivo dell'elenco A, allegato II / Device of List A, Annex II
☐ Produkt der Liste B, Anhang II / Dispositif de la liste B, annexe II / Dispositivo dell'elenco B, allegato II / Device of List B, Annex II
☐ Produkt zur Eigenanwendung, das nicht in Anhang II genannt ist / Dispositif destiné à l'autodiagnostic non listé dans l'annexe II / Dispositivo per test autodiagnostico non elencato nell'allegato II / Device for self-testing not listed in Annex II
☒ Sonstiges Produkt / Autre dispositif / Altro dispostivo / Other device

allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entspricht, die anwendbar sind.

remplit toutes les exigences de la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE qui le concernent.

soddisfa tutte le disposizioni della direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE che lo riguardano.

meets all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.

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Angewandte Gemeinsame Technische Spezifikationen, harmonisierte Normen, nationale Normen oder andere normative Dokumente Spécifications techniques communes, normes harmonisées, normes nationales et autres documents normatifs appliqués Specifiche tecniche comuni, norme armonizzate o nazionali applicate, altri documenti normativi applicati Applied common technical specifications, harmonised standards, national standards or other normative documents	
Konformitätsbewertungsverfahren Procédure d'évaluation de la conformité Procedimentodi valutazionedellaconformità Conformity assessment procedure	Annex III
Konformitätsbewertungsstelle (falls beigezogen) Organe respons. de l'évaluat.de la conformité(si consulté) Organo incaric. della valutaz. della conform. (se consultato) Notified Body (if consulted)	N/A
Ort, Datum / Lieu, date / Luogo, data / Place, date	Name und Funktion / Nom et fonction /Nome e funzione / Name and function
Genève le 19 Juin 2008	

Philippe Daire
RA & QA

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1. INSTALLATION

1.1 UNPACKING

1.1.1 Introduction

The **MYTHIC 22 CT** is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories by an authorized people.

- Only human blood or artificial control blood should be run.
- Only the reagents mentioned in this manual are permitted to be used.
- The optimum performances can be only achieved if the cleaning and maintenance procedures are carefully followed.

If the MYTHIC 22 CT has been stored at a temperature lower than 10°C it must be let at room temperature during 24 hours.

1.1.2 Unpacking Procedure

Before unpacking the instrument, we recommend to check the box of the instrument and notify any damage to the carrier.

- Open the box on the top, remove the starter kit.
- Remove the **MYTHIC 22 CT** from the box.

Starter kit contents :

INSTALLATION KIT	
QTY	**Designation**
1	Tubing 23 - DILUENT
1	Tubing 24 - WASTE
1	150W switching adapter
1	European Power line cord
1	MYTHIC 22 CT User manual
1	MYTHIC 22 CT Installation Report form
1	MYTHIC 22 CT Quality Control Certificate
1	Screwdriver Slot 1/4"

MAINTENANCE KIT	
QTY	**Designation**
1	Tygon tubing L=500mm 1.02mm
1	Tygon tubing L=500mm 1.3mm
1	Tygon tubing L=1000mm 1.52x3.2mm
1	Tygon tubing L=500mm 2.06x4mm
1	Tubing 50
4	Bottle cap filter
1	In line filter
5	Tie wraps
2	Rinsing Head O-ring
1	Silicon grease (3gr)
1	Short Arm TORX T10 Tool
1	Short Arm TORX T20 Tool

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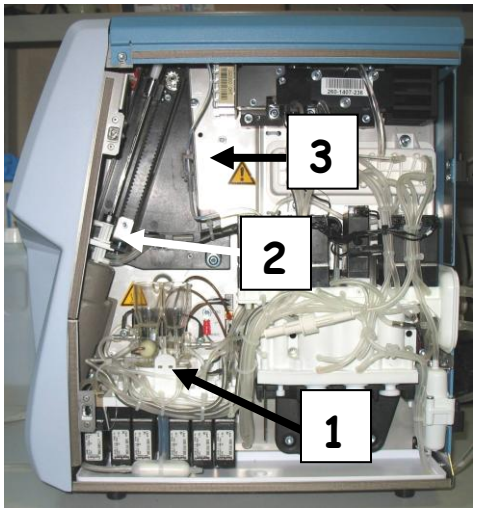
1.1.3 Visual checking

- Open the door on the right side with the key provided in the kit.



To be checked :

1- Counting chambers perfectly locked in their manifold locations.
2- Needle's dismountable system located in the rocker.
3- Rocker in front position at the maximum course.

HAZARDOUS MOVING PARTS, BEWARE TO STAY AWAY FROM THESE PARTS WHEN THE MACHINE IS SWITCH ON.

1.2 INSTALLATION CONSTRAINTS

1.2.1 Installation place

To ensure that the **MYTHIC 22 CT** fulfills its function, place the instrument on a table which supports the weight of the instrument, printer and reagents (around 40 Kg). Leave a space of 10 cm in the rear of the instrument to ensure a well-ventilated place. Avoid a place that can be exposed to direct sunlight.

1.2.2 Installation environment

a) Indoor use;
b) Altitude up to 2 000 m;
c) Temperature 18 °C to 34 °C;
d) Maximum relative humidity 80 % for temperatures up to 31 °C decreasing linearly to 50 % relative humidity at 40 °C;
e) MAINS supply voltage fluctuations up to ±10 % of the nominal voltage;
f) Transient over voltages typically present on the MAINS supply.
g) Rated pollution degree II.

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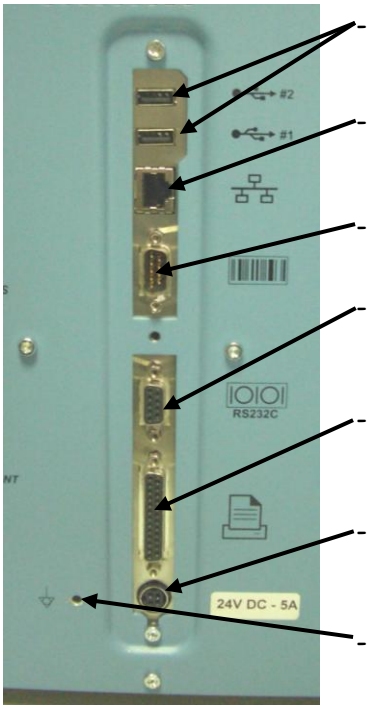
Please contact Orphée's representative if you want to use the instrument in special conditions (altitude higher than 2000 m or special power supply conditions).

1.3 ELECTRICAL CONNECTIONS

All the connectors are in the rear of the **MYTHIC 22 CT**



CONNECTION : SYMBOL :

- 2 USB ports :
- Ethernet connection (TCP/IP) :
- External barcode reader (RS232C) :
- Host connection (RS232C) :
- Printer connection (Centronics) :
- Power supply cord connection : 24V
- Equipotentiality :

⚠	**Any output or input connections (except the printer and the bar code reader supplied by ORPHEE) cannot be done without the ORPHEE representative authorization.**

1.3.1 Power supply block

MYTHIC 22 CT must be connected to the power with the power supply block provided with the starter kit. Choose a well-ventilated place for the block and be sure to connect this power supply in a socket-outlet with a correct earth connection.

The power supply block must be placed at the rear of the **MYTHIC 22 CT** and, if possible in an upper position to avoid the contact with any liquid.

To disconnect electrically the **MYTHIC 22 CT**, remove the power supply plug from the main circuit.

⚠	**In case of replacement of the main power wire, supplied with the MYTHIC 22 CT, the new one must comply with the local regulation (3×1.5mm cable and 250V 10A plug).** **The MYTHIC 22 CT has been certified with the power supply provided with the machine. If another power supply is used with the instrument, Orphée or its representative will not apply any warranty on this power supply and on the instrument. Please contact Orphée or its local representative before to use such material.**

1.4 PRINTER CONNECTION

Connect the printer cable in conformity with the printer user's manual.

Use the parallel rear plug of the **MYTHIC 22 (**) or the USB plug ( ) to connect the printer cable. Select the printer driver (section 3.3).

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1.5 CONNECTION, CHANGE AND PRIMING REAGENTS

MYTHIC 22 CT works exclusively with the reagents described in section 4.3. Orphée or its local representative will not be responsible of the quality of the results and of the maintenance of the instrument if other commercial reagents are used.

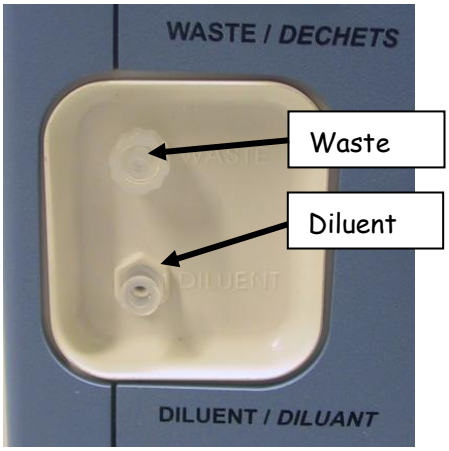
1.5.1 Connection

Lytic reagent and cleaning solution :

Before handling the reagents, read carefully their specifications described in section 4.3.

- Remove the door on the left side of the instrument.
- Put the reagent bottles in the dedicated location.
- Remove the caps of the bottles.
- Tighten the red caps on the OnlyOne bottle (red sticker) and the blue one on the cleaning solution bottle (blue sticker).

Diluent and waste :



- Connect the diluent tube (male connector) on the outlet on the bottom and tighten the cap on the diluent container.
- To use a 20 liter diluent container add the tubing straw adaptor supplied with the installation kit.
- Connect the waste tube (female connector) on the outlet on the top and tighten the cap on an empty container.

- **Do not modify the type and the length of the diluent and waste tubes.**
- **The diluent must be placed on the same level as the MYTHIC 22 CT.**

It is mandatory to collect the waste in a container and to treat it in compliance with your local regulation.

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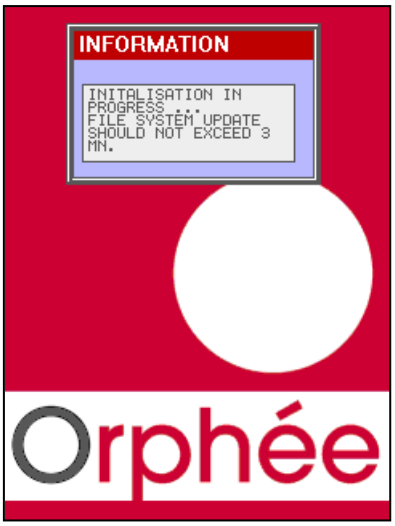
1.5.2 Priming

To use the **MYTHIC 22 CT for the first time**, it is necessary to perform a complete prime of the fluidic circuit. This operation should be done by a Field Service Engineer.

	Before starting, be sure that all the reagent and waste tubes are properly connected. The reagents must be stored 24 hours minimum at room temperature before use.

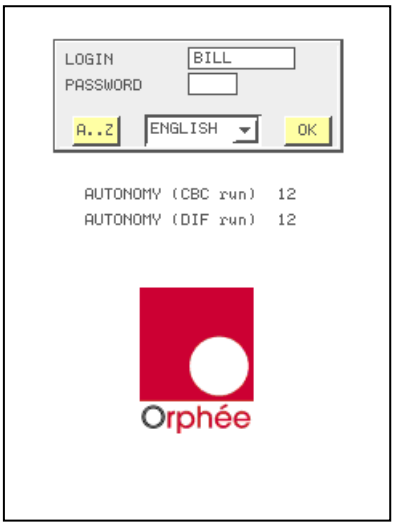
Priming procedure :



① Switch on :

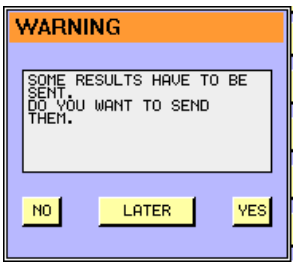
- Connect the power supply block. Switch on the power supply (see section 2.3.4). The power supply can stay switch on all the time.
- Press the ON/OFF button.
- The cycle LED turns red. No cycle can be performed before it turns green.

- The information window could stay up to 3 min to enable the update of all the files.

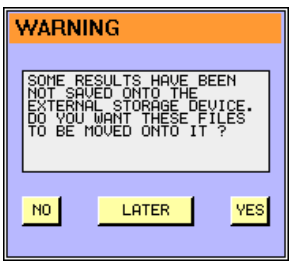


② Login :

- The operator's identification display appears.
- Enter the user's identification, the password (see section 3.1) and press OK to validate.
- **AUTONOMY (run)** indicates the number of samples (runs) you can perform (calculated with the smaller volume of reagents).



- If this window appears, it means that several results in memory have not been sent before the MYTHIC 22 was switched off.
- Press YES to send them immediately, or press LATER to postpone them or NO if you do not want to send them.


WARNING
SOME RESULTS HAVE BEEN NOT SAVED ONTO THE EXTERNAL STORAGE DEVICE. DO YOU WANT THESE FILES TO BE MOVED ONTO IT ?
NO
LATER
YES

- No USB key is available, connect an USB key then press YES or see section 3.4.7 to change the archive mode.

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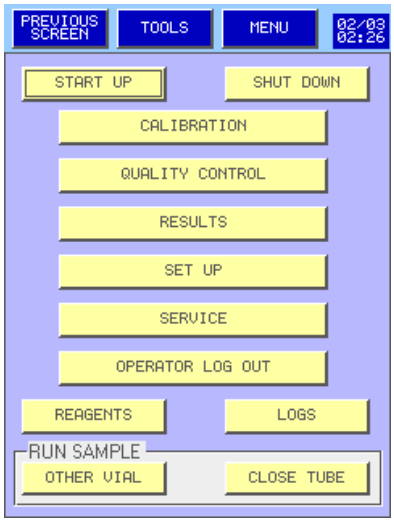
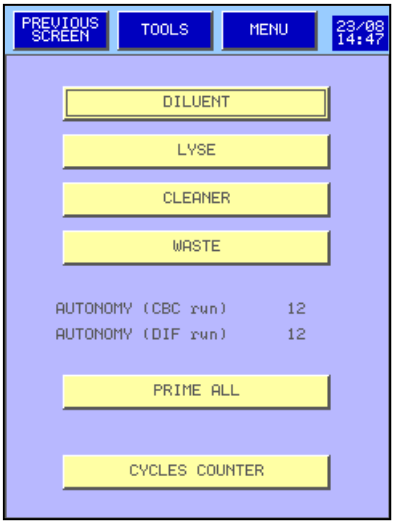


③ <u>System priming</u> :

- The main menu is displayed.
- Press on REAGENTS.

NOTA	To do an emergency stop in case of problem push shortly on the on/off button

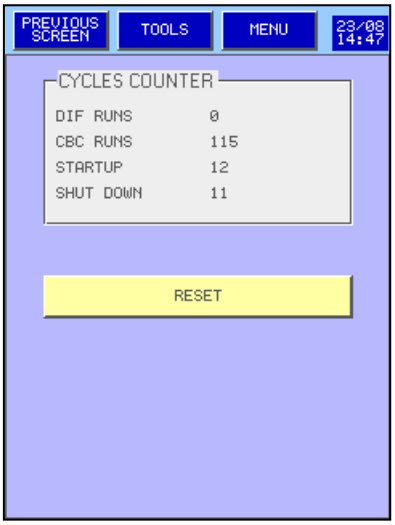


- Press PRIME ALL : The **MYTHIC 22 CT** performs a complete priming cycle.

- The cycle LED turns red. No cycle can be performed before it turns green.

- **AUTONOMY (run)** indicates the number of samples (runs).
- To prime or to know the quantity of reagent press the dedicated button.

- Press CYCLES COUNTER to display the cycle counters.



- To reset the counter with the button RESET, please contact your Orphée's representative.

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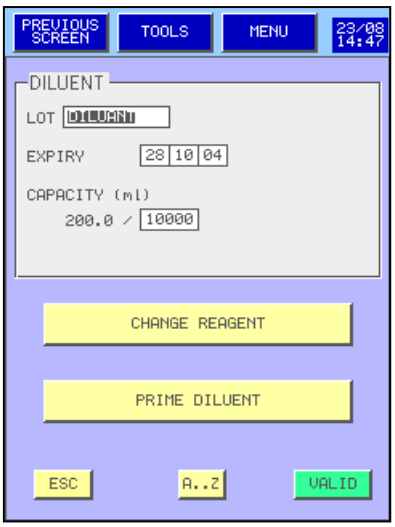
DILUENT PRIME:



- From the **MAIN MENU** press REAGENTS then DILUENT to have access to this screen.

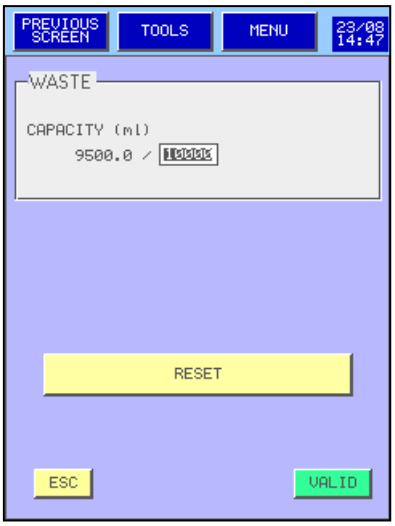
- Enter lot number, the expiry date and the container capacity.

- Press CHANGE REAGENT to validate the new entry or after changing a new container with the same information.
- If needed enter the container volume in milliliter.
- After the replacement of a new container or to prime the diluent, press PRIME DILUENT

- A new entry is automatically done in the logs (see section 5.9)

LYSE AND CLEANER PRIME:
Proceed as described above for the diluent.

WASTE :



- Enter only the capacity of the container.

- After replacement of the waste container press RESET to initialize the waste calculation.

MYTHIC 22 CT IS NOW READY TO WORK.

1.6 TRANSPORTATION AND STORAGE

Storage temperature: -10°C to +50°C.
If the **MYTHIC 22 CT** has been stored at a temperature lower than 10°C it must be left at room temperature during **24** hours.
Before transportation outside the laboratory, perform a complete cleaning with a disinfectant in compliance with the local regulation.

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2. GENERAL OVERVIEW

2.1 GENERALITIES

MYTHIC 22 CT is a fully automated analyzer performing hematological analysis on whole blood collected on EDTA K2 or K3 tubes .

- Sampling volume : 18,2 µl
- Two sampling mode : closed tube or other vial
- Throughput: close tube mode: > 40 samples/hour
  other vial mode: > 45 samples/hour
- 22 analysis parameters in DIF mode and 12 parameters in CBC mode :

Leukocyte parameters :

WBC	White Blood Cells
LYM	Lymphocytes in % & # (DIF mode only)
MON	Monocytes in % & # (DIF mode only)
NEU	Neutrophils in % & # (DIF mode only)
EOS	Eosinophils in % & # (DIF mode only)
BAS	Basophiles in % & # (DIF mode only)

Erythrocyte parameters

RBC	Red Blood Cells
HGB	Hemoglobin
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red Blood cells Distribution Width

Thrombocyte parameters

PLT	Platelet
MPV	Mean Platelet Volume
PDW*	Platelet Distribution Width
PCT*	Thrombocrit

* For Investigation Use only in the United States of America

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2.2 OVERVIEW

MYTHIC 22 CT consists of 8 main parts:

1. Display / Keyboard.
2. Dilution hydraulic part.
3. Mono electronic board.
4. Reagent tray.
5. Connection.
6. External power supply block.
7. Printer.
8. Barcode reader (option).

2.3 MAIN PART DESCRIPTION

2.3.1 Display / Keyboard

Stand By and ON/OFF button

Numeric keyboard

Delete (DEL)

Exit (ESCAPE)

Cursors

Enter (ENTER)

Cycle in process Led

Touch screen LCD display 380*240

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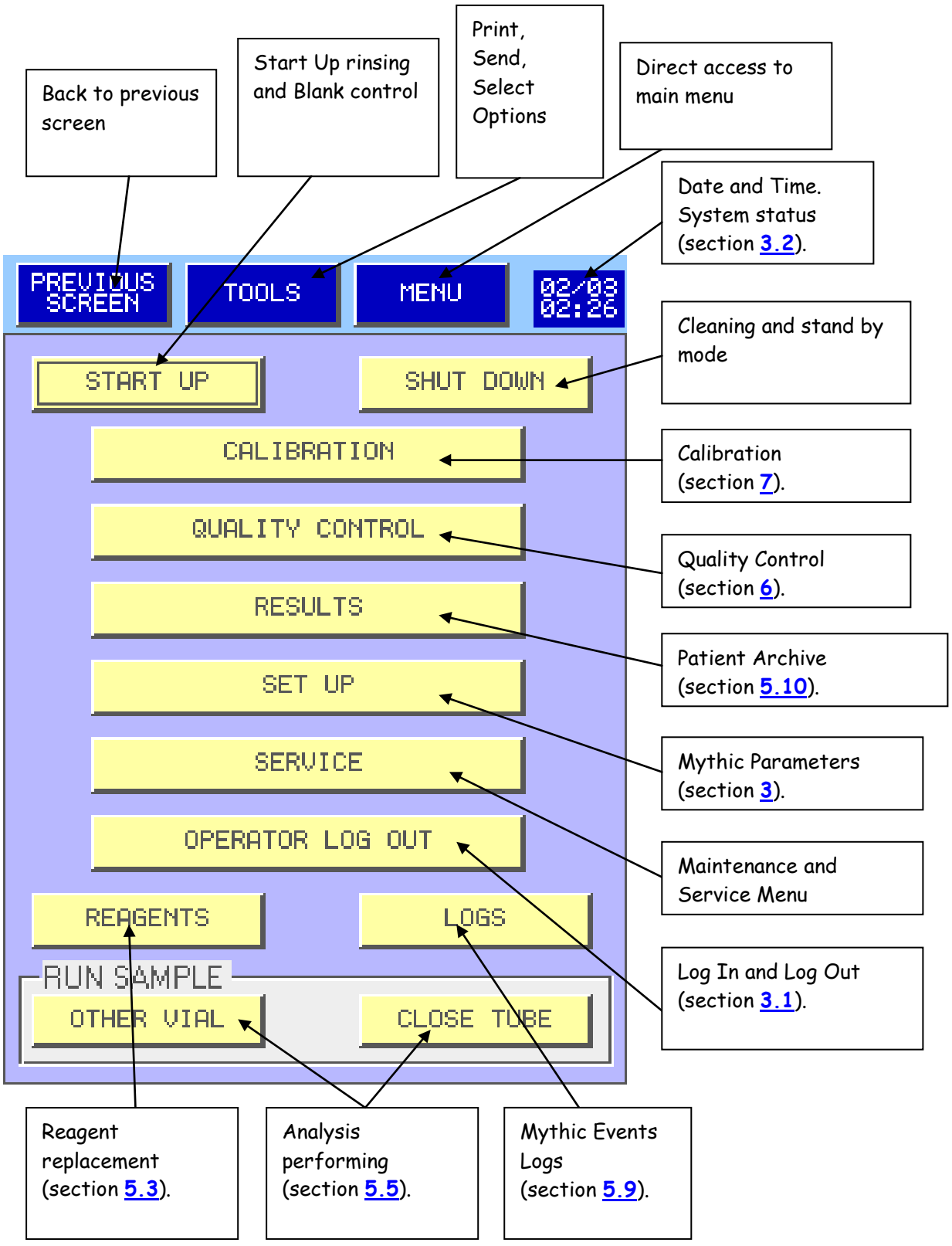
Main Menu description



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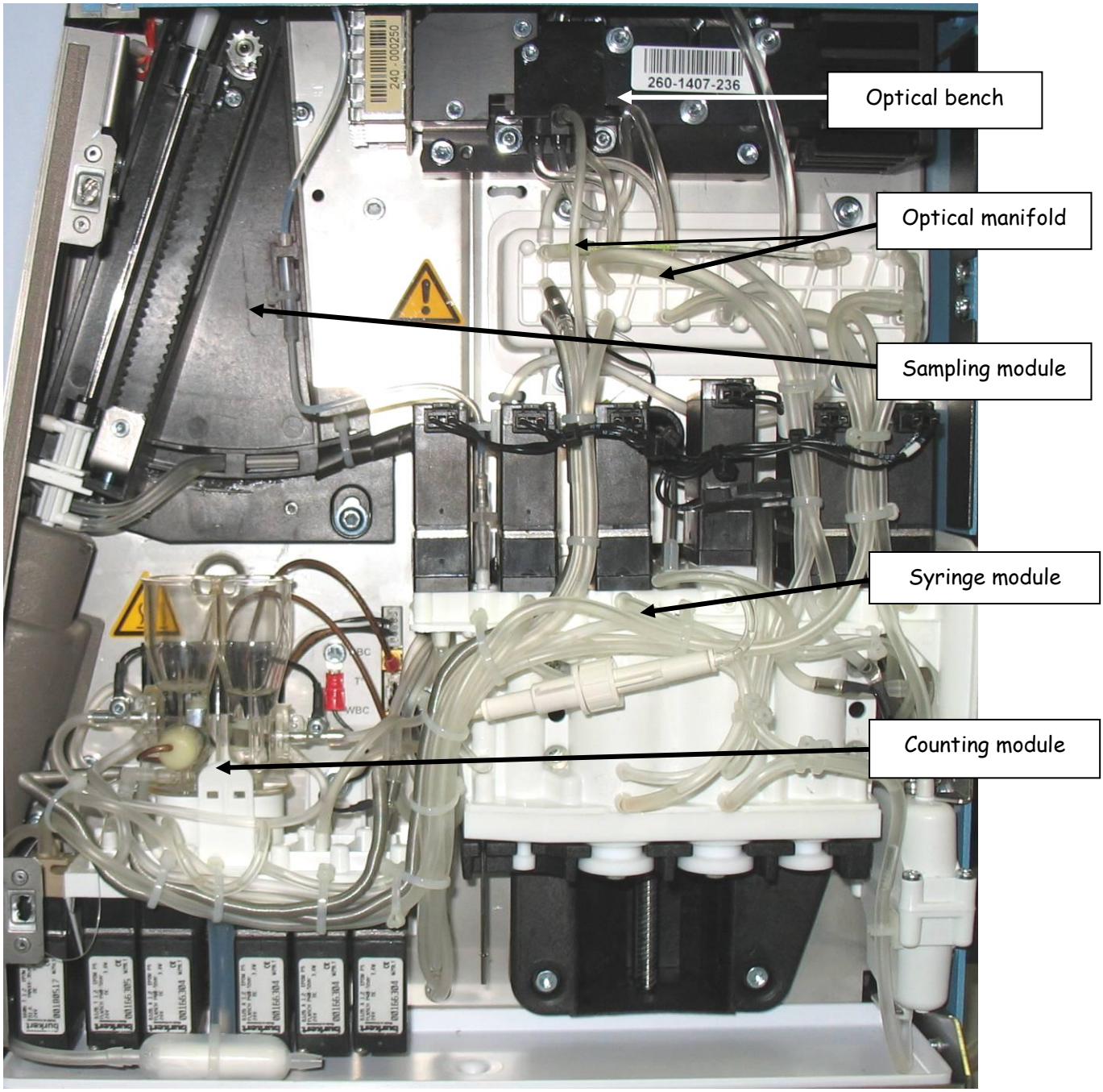
2.3.2 Dilution fluidic part

All the fluidic part is on the right side of the instrument and consist of only three modules:

- Sampling module :
  - Rocker (patented) : Manages the rise and descent of the needle.
- Syringe module (patented) consists of one block :
  - Reagent syringes (Diluent, lysis), sampling and air syringes.
  - Liquid valve manifold assembly and tubing.
- Counting chambers :
  - WBC and RBC counting chambers and hemoglobin measurement.
  - Liquid valve manifold assembly and tubing.



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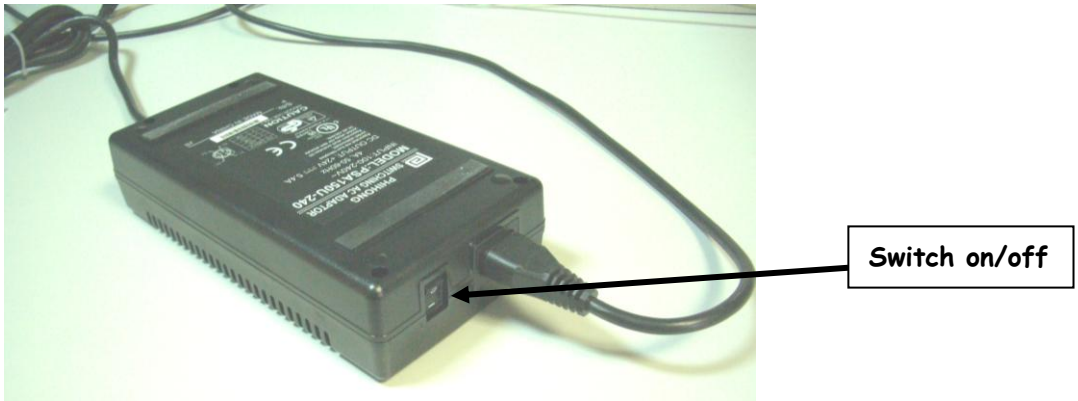
2.3.3 Mono electronic board

The mono electronic board is located between the hydraulic part and the reagent tray.
The board, driven by a 32-bit processor, manages the following parts :

- Sample needle, rocker, syringe block motors.
- Display and keyboard.
- Connexion mode (RS232, Ethernet, …).
- Printer.
- Measurement (Counting, hemoglobin measurement).
- Data processing.
- External barcode reader.

	To avoid all deterioration risks, only the field service engineer can touch this electronic board.

2.3.4 Power Supply Block



MYTHIC 22 CT is supplied with an external power supply block.

	- In the case of replacement of the main power wire supplied with the MYTHIC 22 CT the new one must be in compliance with the local regulation. **- The MYTHIC 22 CT has been certified with the power supply box provided with the machine. - If another power supply is used with the instrument, Orphée or its representative will not apply any warranty on this power supply and on the instrument. Please contact Orphée or its local representative before to use such material.**

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2.3.5 Reagent tray

The reagent tray is dedicated to the OnlyOne lysing reagent and cleaning solution bottles.

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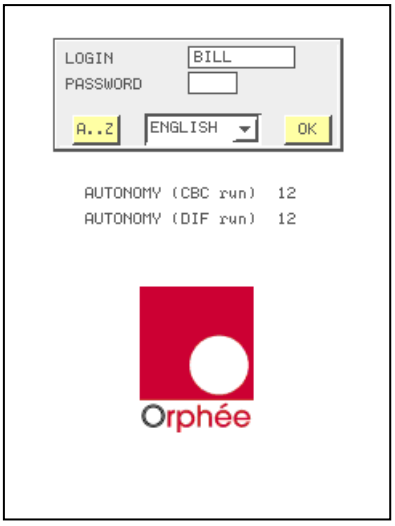
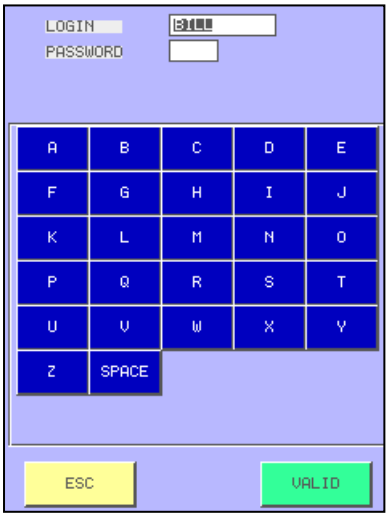
3. INSTRUMENT SET UP

3.1 USER'S IDENTIFICATION

3.1.1 Start Up

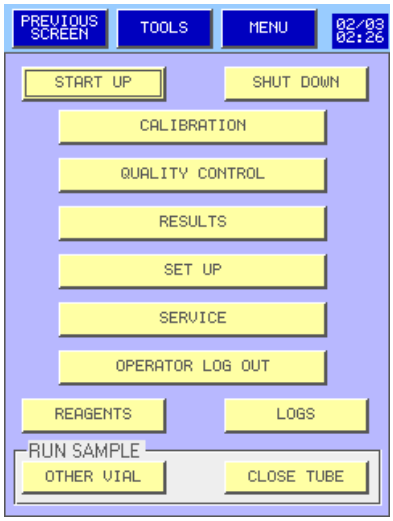


- After the instrument's initialization, the identification window is displayed.
- In the window LOGIN BILL, the last operator's identification appears.
- Either the identification is yours, press PASSWORD and enter your password or the identification is not, press A..Z to enter your login.
- The window ENGLISH enables to change the language. Press OK to validate it.
- **AUTONOMY (run)** indicates the number of samples (runs) you can perform (calculated with the smaller quantity of reagents).



- Enter your identification name with the alphabetic keyboard.
- Place the cursor in the Password window.
- Enter your password for identification.
- For the first login, **MYTHIC 22 CT** proposes 3 access levels :
  - **User** : No password
  - **Biologist** : Password by default **1- 2- 3**
  - **Service people**
- Biologist Password can be modified in section 3.3.6.

3.1.2 In process



- To change operator during the process, press MENU to return to the main menu, and then press on OPERATOR LOG OUT

- To change identification, proceed as described above (section 3.1.1).

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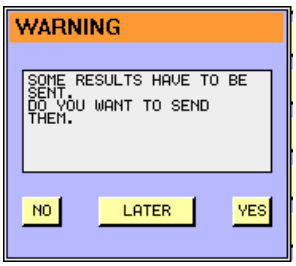
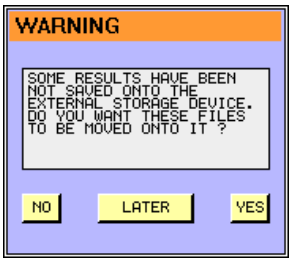
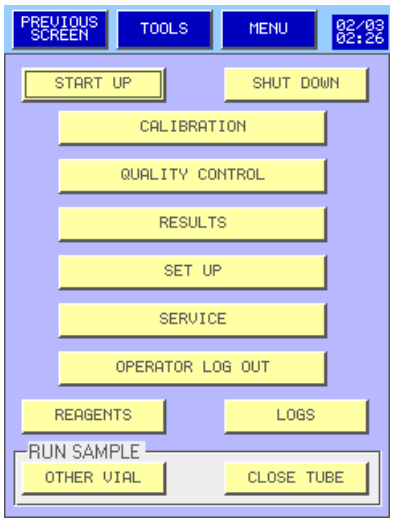


- If this window appears, it means that several results in memory have not been sent before the MYTHIC 22 was switched off.
- Press YES to send them immediately, or press LATER to wait NO if you do not want to send them.

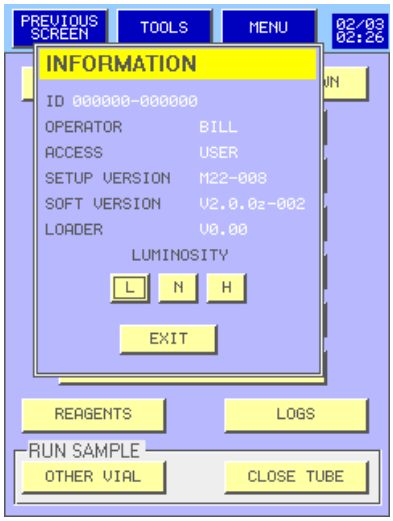

WARNING
SOME RESULTS HAVE BEEN NOT SAVED ONTO THE EXTERNAL STORAGE DEVICE.
DO YOU WANT THESE FILES TO BE MOVED ONTO IT ?
NO
LATER
YES

- No USB key is available, connect an USB key then press YES or see section **3.4.7** to change the archive mode.

3.2 SYSTEM STATUS

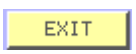


- Press on the date and hour to have access to the system status window.



- Different system status information are displayed.

- To change the screen luminosity press **L** , **N** or **H**

- To return to the **MAIN MENU** press 

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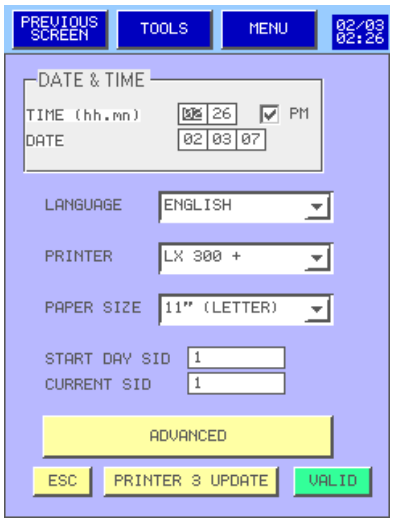
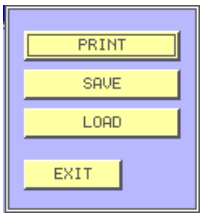
3.3 SET UP



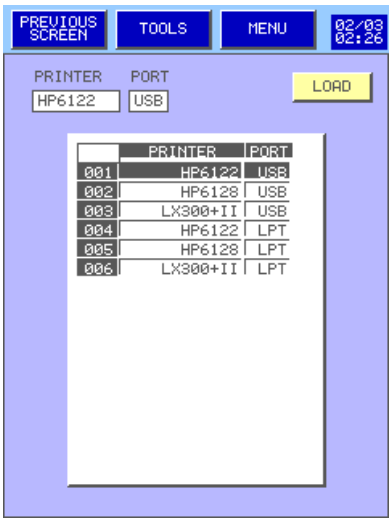
- From the **MAIN MENU** press on SET UP
- This menu is available for all users.
- The **DATE & TIME** window enables to modify the time and the date
- To select the language of the Mythic menu, choose the right one in the Language combo box. LANGUAGE ENGLISH
- PRINTER LX 300 + : Select the printer or no printing.
- PAPER SIZE 11" (LETTER) : Select the paper size per result.
- START DAY SID 1 : Two SID are available; Start day SID enables to select the first SID for each new day.
- CURRENT SID 1 : If you want to select a new SID number
- ADVANCED : Biologist reserved for complete settings. (See section 3.4).

- Once modifications are done, press either VALID to valid or ESC to exit keeping the previous setting.

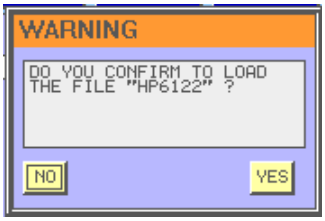


- Press TOOLS to print, save or load from an USB key all the set up.

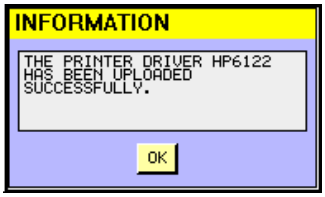
- To load new printers drivers plug the USB key then press on PRINTER 3 UPDATE in the previous screen.



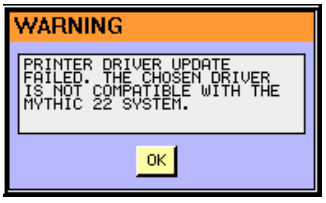
- Select the printer and his connection mode.
- Then press LOAD



- Press YES then, the driver is loaded in the MYTHIC 22CT



This prompt appears to confirm the Driver update.



- This prompt appears if the release is failed, check the USB connection or change the USB key or call your Orphée's representative.

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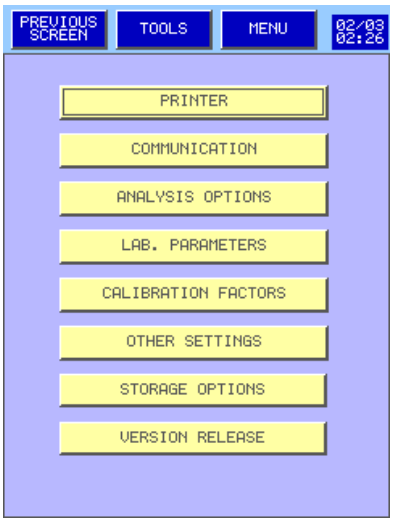
3.4 ADVANCED SET-UP

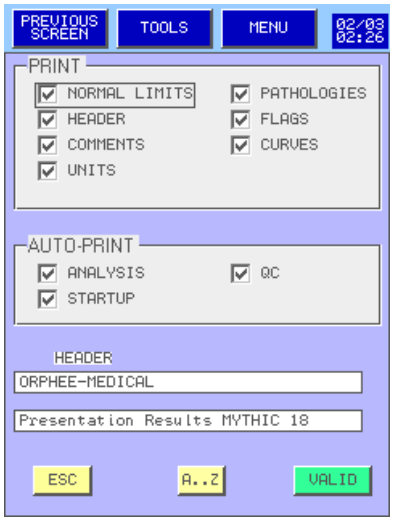


- **This menu is reserved to biologist** (see section 3.1).

	Any modifications can affect the quality of the results. We recommend modifying these values only after an Orphée's training.

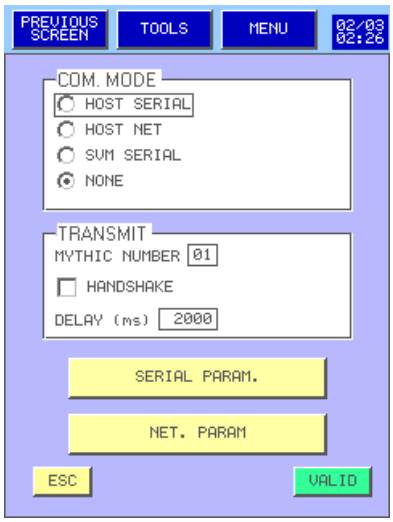
- Please refer below for the description of each key.

3.4.1 Printer set up :



- Printer set up menu is intended to present the printing report
- To select an option on the report, press on the corresponding case.
- To enter a header, press A..Z key.
- To exit the menu, either press ESC to keep the last setting, or VALID to save the last modifications.

3.4.2 Communication:



- Reserved for Field Service Engineer.
- To set up the connection between **MYTHIC** and Host.

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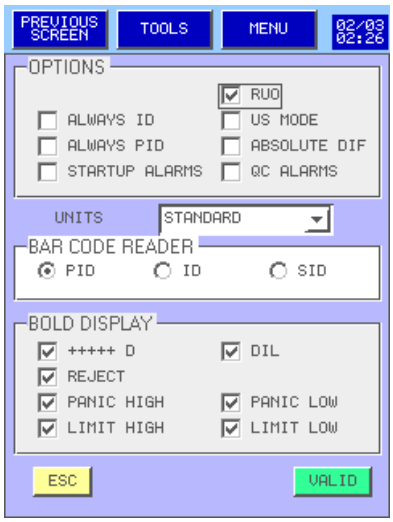
3.4.3 Analysis options:



- **OPTIONS** box:
  - **ALWAYS ID** and **ALWAYS PID**: To run a sample, user mandatory needs to enter a ID and/or a PID.
  - **RUO**: With tag the PCT and PDW parameters are displayed, printed and send.
  - **US MODE**: The Research Use Only message is printing below the printing report.
  - **ABSOLUTE DIFF**: With tag absolute values for sub-populations of leucocytes are displayed. In the other case, percentages are displayed.
  - **QC ALARMS**: The message "QC failed" appear below the printing report when the QC result is out of tolerance or expired; The message "QC not done" appear below the printing report when it is not run.

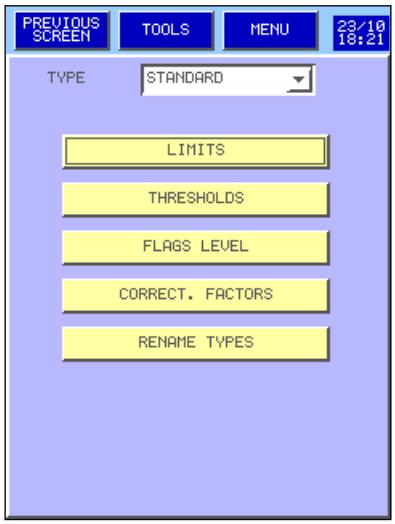
- UNITS STANDARD : Gives a choice of three unit systems: Standard, International System, and mmol.

- **CDB** box: The bar code reader is dedicated to the PID or ID or SID.

- **BOLD DISPLAY** box: display and print in bold-faced type the different choices in this box.

Once modifications are done, press either VALID to validate your choices or ESC to exit keeping the previous setting.

3.4.4 Lab. parameters:



- Select the blood type in the combo box TYPE STANDARD then press:

LIMITS to adjust the normal and panic limits (see section **3.4.4.1**).

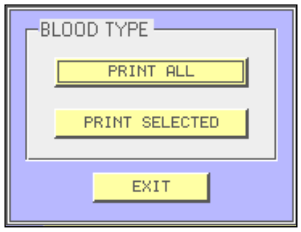
THRESHOLDS to adjust the parameters thresholds (see section **3.4.4.2**).

FLAGS LEVEL to adjust the flags level (see section **3.4.4.3**).

CORRECT. FACTORS to adjust the corrections factors (see section **3.4.4.4**).**NOTA**: No correction factors with type STANDARD.

- To enter a new blood type, press RENAME TYPES

NOTA: The name of the first type STANDARD cannot be change.



- Press TOOLS to print the blood type set up.
- PRINT ALL allow to print all the blood type set up (about **20** pages are printed)
- PRINT SELECTED only the blood type in the combo box is printed.

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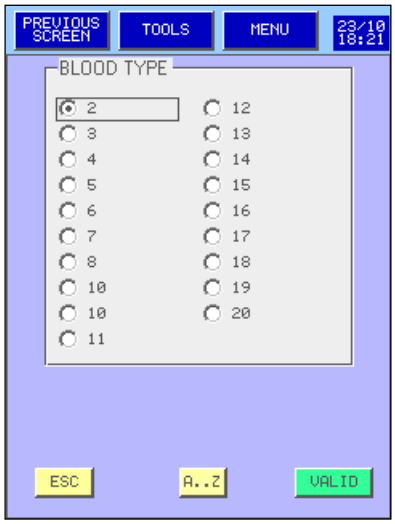
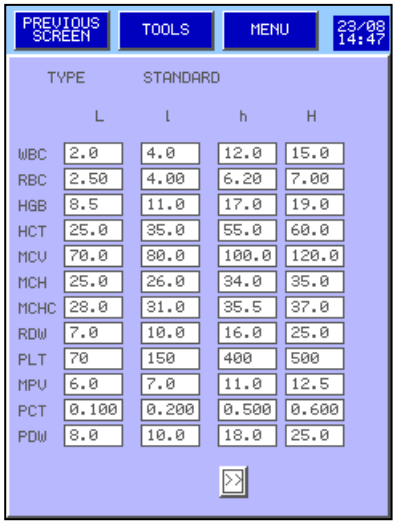


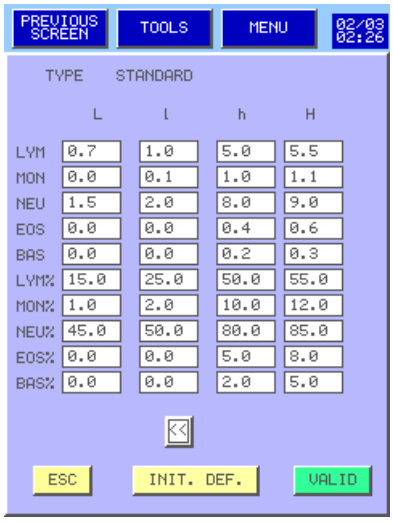
To rename a blood type press RENAME TYPES then select it then press A..Z to accede at the alphabetic keyboard then press VALID to validate or ESC to exit without any modification.

3.4.4.1 Limits :



- This display enables to enter normal and panic limits for every 22 parameters given by the **MYTHIC 22 CT** (see section 8).

- To validate the new values, press VALID key in the next page (see below).



- Once modifications are done, press VALID to validate or ESC to exit without any modification.

- Press INIT. DEF. to return to the parameter setting of the standard type.

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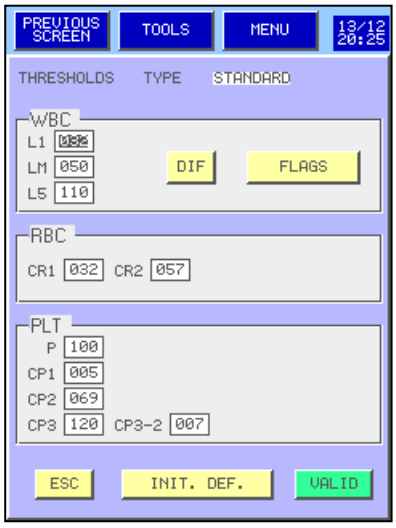
Example of reference values from **LABORATOIRE D'HEMATOLOGIE DU C.H.U. D'ANGERS (FRANCE)**

	First week	8 days to 3 months	3 months to 3 years	3 to 6 years	6 to 15 years	Adult
WBC $10^3/\mu L$ ($10^9/L$)	10,0 to 30,0	6,0 to 18,0	6,0 to 15,0	5,0 to 13,0	5,0 to 11,0	4,0 to 10,0
Neutrophils ($10^3/\mu L$)	6,0 to 26,0	1,5 to 8,5	1,5 to 8,5	1,5 to 8,5	1,8 to 8,0	1,8 to 7,5
Eosinophils ($10^3/\mu L$)	0,2 to 0,85	0,2 to 1,2	0,05 to 0,7	0,02 to 0,65	0 to 0,6	0,04 to 0,8
Basophils ($10^3/\mu L$)	0 to 0,64	0 to 0,2	0 to 0,2	0 to 0,2	0 to 0,2	0 to 0,2
Lymphocytes ($10^3/\mu L$)	2,0 to 11,0	2,0 to 11,0	4,0 to 10,5	2,0 to 8,0	1,5 to 6,5	1,0 to 4,5
Monocytes ($10^3/\mu L$)	0,4 to 3,1	0,05 to 1,1	0 to 0,8	0 to 0,8	0 to 0,8	0,2 to 1,0
RBC $10^6/\mu L$ ($10^{12}/L$)	5,0 to 6,0	3,8 to 4,8	3,6 to 5,2	4,1 to 5,3	4,0 to 5,4	M : 4,5 to 5,8 F : 3,8 to 5,4
HGB g/dL	14,5 to 22,5	10 to 16	10,5 to 13,5	10,5 to 13,5	11,5 to 14,5	H : 13,5 to 17,5 F : 12,5 to 15,5
HCT %	44 to 58	38 to 44	36 to 44	36 to 44	37 to 45	M : 40 to 50 F : 37 to 47
MCV fl	100 to 120	85 to 96	70 to 86	73 to 89	77 to 91	82 to 98
MCH pg	34 to 38	24 to 34	23 to 31	24 to 30	24 to 30	> or = 27
MCHC g/dL	32 to 36	32 to 36	32 to 36	32 to 36	32 to 36	32 to 36
PLT $10^3/\mu L$ ($10^9/L$)	150 to 400	150 to 400	150 to 400	150 to 400	150 to 400	150 to 400

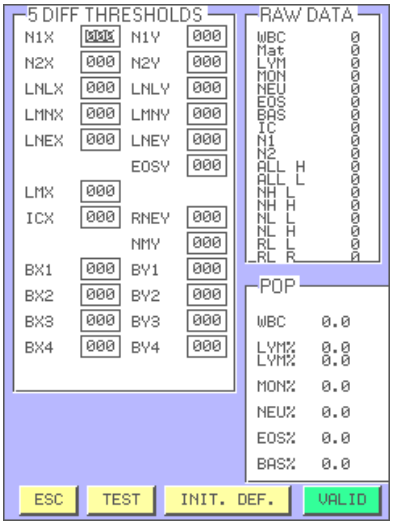
3.4.4.2 Thresholds :



- The threshold display enables to modify the detection thresholds located on the WBC scattergram and RBC, PLT curves (see section 8).

Threshold modifications can affect the quality of the results or can affect the alarm detection area. We recommend modifying these values only after an Orphée's training.

- To accede to modification of the scatter gram threshold press DIF and to the flags threshold press FLAGS.
- Once modifications are done, press VALID to validate or ESC to exit without any modification.
- Press INIT. DEF. to return to the manufacturer parameter setting.



Threshold modifications can affect the quality of the results or can affect the alarm detection area. We recommend to modify these values only after an Orphée's training.

- Press INIT. DEF. INIT. DEF. to return to the manufacturer parameter setting.

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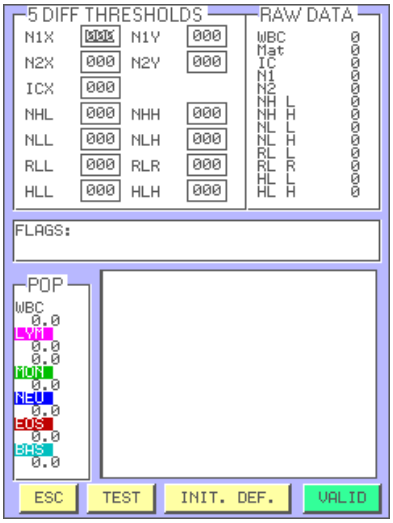
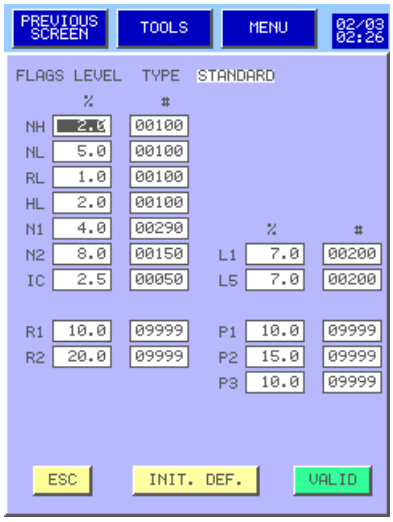


	Threshold modifications can affect the quality of the results or can affect the alarm detection area. We recommend to modify these values only after an Orphée's training.

- Press INIT. DEF. INIT. DEF. to return to the manufacturer parameter setting.

3.4.4.3 Flags level :



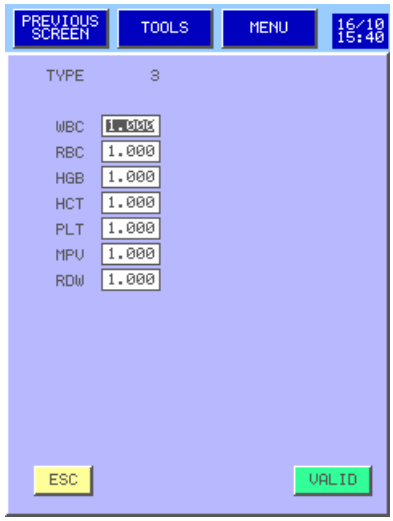
- In the Alarm menu, users can modify the sensitivity of the alarms for the different cells: WBC, RBC, PLT and differential (See section 8.5).

- The WBC flags appear when the % limit **AND** # limit are reached.
- The RBC and PLT flags appear when the % limit **OR** # limit are reached

- Once modifications are done, press VALID to validate or ESC to exit without any modification.

- Press INIT. DEF. to return to the parameter setting of the standard type.

3.4.4.5 Correction factors:



- In this menu, for each blood type, users can define a correction factor which is multiplied by the calibration factor given by a normal calibration (see section 7).

- Once modifications are done, press VALID to validate or ESC to exit without any modification.

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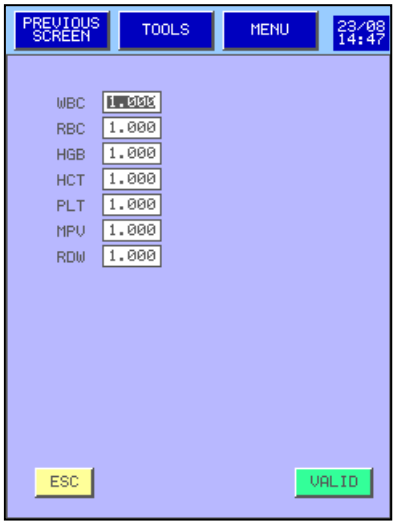
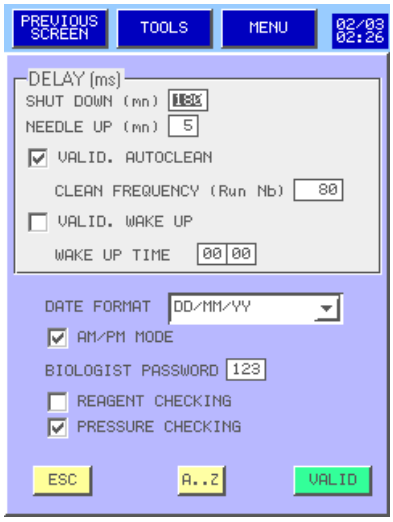
3.4.5 Calibration factor:



- To accede to this menu press CALIBRATION FACTORS in the ADVANCED SET UP MENU (see section 3.4)
- In this menu, the user can modify the calibration factors without any calibration with calibration blood.
- A **M** letter appears on the right of the date of calibration in case of modification in the Calibration Menu.

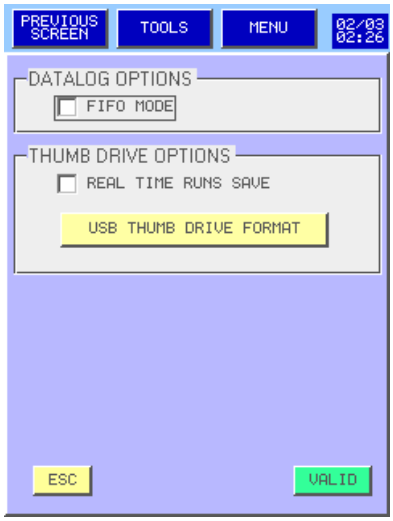
⚠	**The modification of any of these factors without running a calibration blood could affect the quality of the result.**

3.4.6 Other Setting:



- In **DELAY** box, the user can modify:
  - Time in minutes to start the automatic shut down.
  - Time in minutes to buildup the needle.
  - The setting of the automatic cleaning VALID. AUTOCLEAN and its frequency in number of analysis CLEAN FREQUENCY (Run Nb) 80 .
  - The setting of the automatic wake up VALID. WAKE UP and its daily time WAKE UP TIME 14 00
  - Reagent checking enables the reagent control (see section 1.5.2)
  - Pressure Checking is accessible for technician only.
- BIOLOGIST PASSWORD 123 enables to modify the biologist password.
- DATE FORMAT DD/MM/YY enables to select the date format.
- Once modifications are done, press VALID to validate or ESC to exit without any modification.

3.4.7 Storage options :



MYTHIC 22 can save more than the last 1500 patients with results, alarms, distribution curves in the internal memory and until a maximum of 60 000 results in a memory stick (USB key) with capacity from 512 Mb to 2 Gb maximum can be used.
Because the technology of the USB key are very different some of them could not work. For more information contact your Orphée's representative.

- Choose for a FIFO (first in /first out) mode or real time to store the results in the resident memory or in a USB key

- Choose REAL TIME RUNS SAVE to directly save sample run onto USB key. if USB key is available, result will be store at the end of the sample run.

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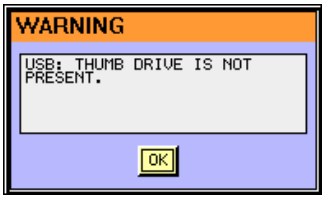
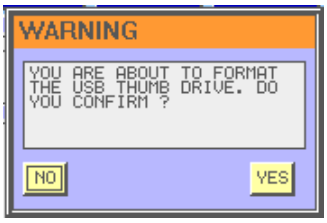
Press USB THUMB DRIVE FORMAT to format USB key. The system will format the USB Key and build specific directories for Mythic management.



- This prompt appears if no USB key is available, or if the USB key is not compatible with the instrument.

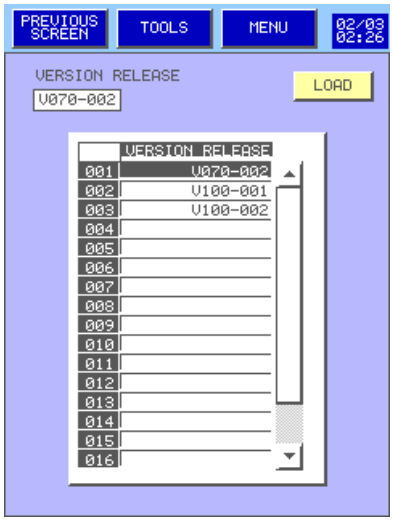


- Press yes if you agree to format the USB key. It is mandatory to format the USB key on the Mythic before to use it.

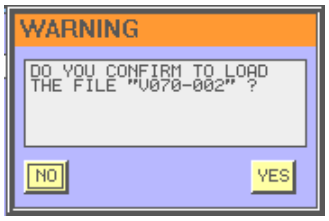
⚠	**All the information includes in the USB key will be erased.**

3.4.8 Version release :

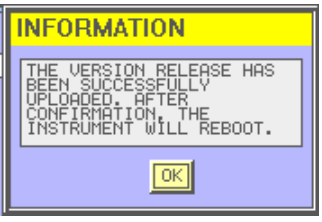
⚠	**Load a new software version only with the agreement of an Orphée's representative. Be sure to load the new upgrade in the right folder on the USB thumb drive. If you have any doubt, please contact Orphée S.A. service department or your Orphée's representative.**



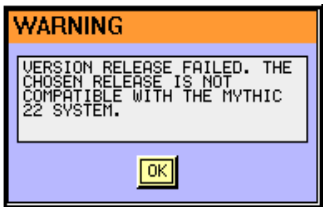
- Press LOAD to load a new software version from a USB key.
- Choose the right version then,
- Press yes only if you are sure to load a new version software.



⚠	**The current software version will be erased definitively and replaced by the new one.**



- This prompt appears to confirm the version is loaded.



- This prompt appears when the release of the software is failed.

- Choose another version or call your Orphée's representative.

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4. SPECIFICATIONS

4.1 ANALYTICAL SPECIFICATIONS

Throughput: Close tube mode: > 40 samples/hour
Other vial mode: > 45 samples/hour

Sampling Volume: 18,2 µl (approx.)

Measurement Principle: WBC/RBC/PLT: Impedancemetry
Five part diff: Optical flow cytometry
Hemoglobin: Spectrophotometry at 555 nm
Hematocrit: Volume integration

Linearity:
Linearity is measured with linearity sample performed four times for each level.

PARAMETERS	RANGE	LIMITS (the larger)
WBC ($10^3/mm^3$)	0 to 100	+/- 0,4 or +/- 4%
RBC ($10^6/mm^3$)	0,1 to 8	+/- 0,07 or +/- 3%
HGB (g/dL)	1,0 to 24	+/- 0,3 or +/- 2%
HCT (%)	5 to 70	+/- 2 or +/- 3%
PLT ($10^3/mm^3$)	5 to 2 000	+/- 10 or +/- 5%

Reportable range:
Within the reportable range, the results are flagged with a **D** to indicate that it is necessary to re-dilute and re-run the sample.

PARAMETERS	REPORTABLE RANGE
WBC ($10^3/mm^3$)	100 to 150
RBC ($10^6/mm^3$)	8 to 15
HCT (%)	70 to 80
PLT ($10^3/mm^3$)	2000 to 4 000

Repeatability:
Calculated with 20 runs of a fresh whole blood sample performed on a commercial **MYTHIC 22 CT**.

PARAMETERS	CV	RANGE
WBC	< 2,5%	> to $6,0\times10^3/mm^3$
LYM	< 5%	> to 15 %
MON	< 10%	> to 7 %
NEU	< 4%	> to 50 %
EOS	< 10%	> to 5%
BAS	< 40%	> to 2%
RBC	< 2%	> to $4,0\times10^6/mm^3$
HGB	< 1,5%	> to 12,0 g/dL
HCT	< 2%	> to 40,0 %
MCV	< 1%	> to 85 fL
RDW	< 4%	> to 14
PLT	< 5%	> to $250\times10^3/mm^3$
PMV	< 3%	> to 8 fL

Calculated method: $CV = \frac{SD}{\overline{X}}$

$$SD = \sqrt{\frac{\Sigma x^2 - \frac{(\Sigma x)^2}{N}}{N - 1}}$$

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Carry-Over:
For each parameter, we perform 3 runs from a high concentration sample followed by 3 runs without sample.

	WBC	RBC	HGB	PLT
High concentration value	$140\times10^3/mm^3$	$8\times10^6/mm^3$	20g/dL	$3000\times10^3/mm^3$
Measured carry-over (%)	0,29	0,13	0	0,07
Maximum carry-over (%)	< 1,0	< 1,0	< 1,0	< 1,0

The percentage of carry-over inter samples is calculated with the following formula :

$$\text{Carry-over} = \frac{\text{(Low value cycle 1) - (Low value cycle 3)}}{\text{(High value cycle 3) - (Low value cycle 3)}} \times 100$$

Accuracy:
Correlation with one commercial instrument (HORIBA ABX PENTRA 120 ®) and with normal blood samples (without alarm).

	MYTHIC 22		MYTHIC 22 CT	
PARAMETERS	N	R (%)	N	R (%)
WBC ($10^3/mm^3$)	127	0,997	52	0,996
LYM (%)	113	0,989	52	0,974
MON (%)	113	0,935	52	0,974
NEU (%)	113	0,988	52	0,963
EOS (%)	113	0,950	52	0,933
BAS (%)	113	0,187	50	0,093
RBC ($10^6/mm^3$)	127	0,991	52	0,994
HGB (g/dL)	127	0,997	52	0,995
HCT (%)	127	0,984	52	0,990
MCV (fL)	127	0,947	52	0,968
RDW (%)	127	0,746	52	0,903
MCH (pg)	127	0,963	52	0,980
MCHC (g/dL)	127	0,151	52	0,175
PLT ($10^3/mm^3$)	127	0,990	52	0,978
MPV (fL)	127	0,890	52	0,924

Calculated method: $$\mathbf{r} = \frac{n.\Sigma xy - \Sigma x.\ \Sigma y}{\sqrt{(n.\ \Sigma x^2 - (\Sigma x^2))(n.\ \Sigma y^2 - (\Sigma y^2))}}$$

Mode to mode (closed tube and other vial) acceptable differences:

PARAMETERS	MEAN DIFFERENCE (whichever is greater)
WBC ($10^3/mm^3$)	0,5 or +/- 5%
RBC ($10^6/mm^3$)	0,3 or +/- 2%
HGB (g/dl)	0,5 or +/- 2%
PLT ($10^3/mm^3$)	40 or +/- 7%

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4.2 PHYSICAL SPECIFICATIONS

General:
Ambient temperature: from 18 to 34°C
Relative Humidity: 80% maximum at 32°C
Storage temperature: -10 to 50°C

If the MYTHIC 22 CT has been stored at a temperature less than 10°C, it must stay at room temperature during 24 hours before switching it on.

INSTRUMENT:

Dimensions: Height : 350 mm (approx.)
Width : 250 mm (approx.)
Depth : 340 mm (approx.)

Weight: 13kg (approx.)

Power supply Input: 24V –5A DC

Electric consumption: During cycle: 75 VA (-30% +10%)
Stand By: 20 VA (-30% +10%)
Maximum: 110 VA (-30% +10%)

Display: TFT Color LCD 240*320
Mode portrait
Retro-lighted

Barcode (option : Barcode reader: C39/ Barcode / 2 interleaved 5

Memory capacity: > 1500 Files (Demographics, results and histograms in the internal memory)
> 60 000 results in a memory stick (USB key) of 512 Mbit or more
QC: 6 levels (100 Files per level)

Connection: RS 232C
Ethernet (TCP/IP)
USB

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Reagent Consumption (ml): Software Version **> V2.2.0-005**

CYCLES		DILUENT	LYSE	CLEANER
Run Sample	CT DIF	22	0,9	0,45
	CT CBC	14,2	0,73	0,45
	OV DIF	21,5	0,9	0,45
	OV CBC	13,7	0,73	0,45
Rinse All		10,9	--	--
Back flush		11,3	--	0,26
Control		14,8	--	0,45
Reagent	All	40	4,5	5,6
Prime	Lysis OnlyOne	5,7	6,6	--
	Diluent	30	--	--
	Cleaner	--	--	3,5
Cleaning		12,8	0,2	5,2
Bleach		48,5	1,1	0,45
Start Up *		56,1	3,1	0,45
Shut Down		6,9	0,5	22
Latex WBC		14.5	1.10	0.45
Latex RBC		7.10	--	--
Latex OPT (1)		13.00	0.9	--
Latex OPT (2)		13.00	0.9	--
Latex OPT (3)		13.00	0.9	--
Optical Led		1.00	0.10	--

***** Consumption with one run sample, add one or two run sample CT DIF consumption if needed.

POWER SUPPLY BLOCK:

Dimensions: Height: 55 mm
Width: 127 mm
Depth: 230 mm
Weight: 1,32Kg
Power supply Input:: 100 to 240VAC (2A/230VAC at maximum load – 4A/115VAC at maximum load)
50-60Hz

PRINTER (LX-300+)(option):

Dimensions: Height: 164 mm (approx.)
Width: 366 mm (approx.)
Depth: 275 mm (approx.)
Weight: 4,4 kg (approx.)
Power supply: Model 120V — 99 to 132Vac — 50 to 60 Hz; Model 220-240V — 198 to 264Vac
Electric consumption: 23W (approx.)
Paper size: A4
Printer: Impact (9 needles)
Speed: Up to 300 cps (character per second)

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4.3 REAGENTS SPECIFICATIONS

All the reagents must be stored at room temperature (18°C to 25°C).

4.3.1 Diluent

ORPHEE code number: **HM22-003-10**
Opening shelf life: 60 days.

Application: The diluent is used to carry out the necessary dilutions for the measurement performed by the **MYTHIC 22 CT**.(see section **8**)

Active components: Solid content: 0,9%.

Others components: Buffer.
Preservative.

Description: Clear and odorless aqueous solution.

Storage: At room temperature until the expiry date labeled on the bottle.

Precautions: Can cause skin and eyes irritation. Wear a smock, gloves and glasses during manipulation.

First emergency care:

Inhalation: Breathe fresh air ; seek for medical advice in case of persisting symptoms
Eyes: Abundantly rinse opened eye during 15 mn.
Skin: not skin irritating.
Ingestion: rinse out mouth ; seek for medical advice in case of persisting symptoms.

Accidental release and disposal measure :

Person related safety precautions:	Wear protective equipment; keep unprotected persons away
environmental protection:	Do not allow product to reach sewage system or water bodies
cleaning/collecting:	Absorb with liquid-binding material (sand diatomite, acid binders, universal binders, saw dust) Comply with local and/or federal disposal legislation

If any doubt, call an emergency center.

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4.3.2 Lytic reagent "OnlyOne"

ORPHEE code number: **HM22-002-1**
Opening shelf life: 60 days.

Application: OnlyOne Lytic reagent is used as unique leukocyte and hemoglobin reagent to lyse red blood cells, enable cells subpopulations differentiation and counting and quantitatively determine hemoglobin content of blood samples on **MYTHIC 22 CT**, (see section 8)

Active components:
- alkaline salts and buffering means
- ionic and non-ionic surfactants mix
- Leuko-protective agents
- non toxic Hemoglobin chelate
- Preservatives

Description: A clear pale yellow aqueous solution (with slight characteristic smell) composed of alkaline salts, inorganic buffers, leukoprotective agents, detergents, a non toxic hemoglobin stabilizing chelate, and preservatives

NOTA: This reagent does not contains any cyanide, neither formaldehyde, nor azide.

Storage: At room temperature, until expiry date labeled on the bottle.

Precautions: Can cause skin and eyes irritation. Wear a smock, gloves and glasses during manipulation.

First emergency care:

Inhalation: Breathe fresh air ; seek for medical advice in case of persisting symptoms
Eyes: Abundantly rinse opened eye during 15 mn.
Skin: Abundantly rinse during 15 mn ; seek for medical advice in case of persisting symptoms
Ingestion: give large amount of water ; seek for medical advice in case of persisting symptoms.

Accidental release and disposal measure :

Person related safety precautions:	Wear protective equipment ; keep unprotected persons away
environmental protection:	Do not allow product to reach sewage system or water bodies
cleaning/collecting:	Absorb with liquid-binding material (sand diatomite, acid binders, universal binders, saw dust) Comply with local and/or federal disposal legislation

If any doubt, call an emergency center.

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4.3.3 Cleaning solution

ORPHEE code number: **HM22-001-1**
Opening shelf life: 60 days.

Application: The cleaning solution is used to carry out the cleaning of the measurement system and hydraulic circuit (see section **8**).

Components: Enzyme
Propylene glycol 2,5-10%:
dangerous component with critical values that require monitoring at the workplace
(CAS 55-57-6; EINECS 200-338-0)
OES long term value: 474mg/m^3 150ppm total
10mg/m^3 particules
Violet dye.

Description: Clear aqueous solution, violet color, with characteristic smell

Storage: At room temperature, until expiry date labeled on the bottle.

Precautions: Can cause skin and eyes irritation. Wear on a smock, gloves and glasses during manipulation.

First emergency care:

Inhalation: Breathe fresh air ; seek for medical advice in case of persisting symptoms
Eyes: Abundantly rinse opened eye during 15 mn.
Skin: Abundantly rinse during 15 mn ; seek for medical advice in case of persisting symptoms
Ingestion: give large amount of water ; seek for medical advice in case of persisting symptoms.

Accidental release and disposal measures:

Person related safety precautions:	Wear protective equipment ; keep unprotected persons away
environmental protection:	Do not allow product to reach sewage system or water bodies
cleaning/collecting:	Absorb with liquid-binding material (sand diatomite, acid binders, universal binders, saw dust) Comply with local and/or federal disposal legislation

If any doubt, call an emergency center.

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4.4 ANALYTICAL LIMITATIONS

4.3.1 Recommendations

MAINTENANCE:
Please respect the maintenance procedure and the quality control procedure. Otherwise, results can be affected.

GENERALITIES:
Some abnormal samples may give incorrect results by automated cell counting methods. The following table shows examples of specific specimens that could cause errors.

Each result for a new patient out of lab linearity limits or with an alarm must be checked with a conventional method or checked with blood smear.

4.3.1 Interferences

Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22 CT	action
WBC	Cold Agglutinin	(+)	*Cause* : high IgM level may lower RBC and increase MCV *Indication* : ↑MCV, ↓HCT, N1 &/or N2 &/or L1 &/or HL flags	Seek for red cell clumping on Smear
	Nucleated RBC Erythroblastosis	(+)	*Indication* : NRBC may be detected on the WBC scattergram with N1 &/or N2 &/or L1 flags	Seek for NRBC on smear.
	Unlysed RBC	(+)	*Cause:* in some rare instance few erythrocytes may not be completely lysed. *Indication* : lyse-resistant RBC may be detected on the WBC scattergram with N1 &/or N2 &/or L1 &/or HL flags	
	Cryoglobulins	(+)	*Cause:* In association with various pathologies cryoglobulins cause the WBC, RBC, Plt and Hgb to increase *Indication*: high level of all above mentioned items in case of myeloma, carcinoma, leukemia and other proliferative disorders, pregnancy…	Warm the specimen up to 37°C(99°F) for 30min and re-assay immediately after.
	Platelet aggregation	(+)	*Indication* : aggregates may be detected on the WBC scattergram with N1 &/or N2 &/or L1 flags	Seek for Platelet aggregates on smear

(+): Instrument count is affected by an increase in the result.
(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or decrease in the result which is sample dependent.

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Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22 CT	action
LYM (# & %)	Nucleated RBC Erythroblastosis	(+)	*Indication:* NRBC may be detected on the WBC scattergram with N1 &/or N2 &/or L1 &/or HL flags	Seek for NRBC on smear.
	Platelet aggregation	(+)	*Indication:* aggregates may be detected on the WBC scattergram with N1 &/or N2 &/or L1 flags	Seek for Platelet aggregates on smear
MON (# & %)	Large or atypical lymphocytes	(+)	*Cause:* These lymphocytes are larger than normal lymphocytes and tend to overlap the MON clump on the scattergram *Indication:* reduced LYM/MON gap with LYM band RL flags	Seek for Erythroblasts on smear
	Small Neutrophils	(+)	*Cause :* These few segmented and granulations-lacking Neutrophils tend to overlap the MON clump on the scattergram *Indication:* reduced NEU/MON gap with NL flags	
	Lymphoid & myeloid Blasts	(+)	*Cause :* Blasts are large and polymorphic immature cells that may overlap all normal cells clumps *Indication*: reduced/absent LYM/MON even MON/NEU/LYM gap with overlapping population RL &/or NL &/or HL flags	Seek for blasts on smear
	Excessive number of basophils	(+)	*Cause:* in case of basophilia the basophils clump may overlap the MON clump on the scattergram *Indication:* reduced LYM/MON gap RL &/or HL &/or NL flags	Seek for basophils on smear
	Immature monocytes	(+)	*Cause:* Immature monocytic line cells proliferate in certain pathologies (multiple myeloma, monocytic leukemia…) and generate a band at the right of normal MON clump that causes an inaccurate high level of monocytes. *Indication*: : diffuse MON clump with right-end flame population IC &/or L5 &/or NL flags	Seek for immature monocytes on smear
NEU (# & %)	Excessive number of eosinophils	(+)	*Cause:* The excessive presence of eosinophils (eosinophilia) may interfere with NEU counting *Indication:* EOS clump is overlapping NEU clump NH flag	check the eosinophils clump on the scattergram to eliminate eosinophilia
	Immature granulocytes	(+)	*Cause :* metamyelocytes, myelocytes, promyelocytes, blasts or plasma cells are large and polymorphous cells that may overlap NEU clump *Indication:* diffuse spreading out NEU clump NL &/or RL &/or IC &/or L5 flags	Seek for immature cells on smear

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(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or decrease in the result which is sample dependent.

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Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22 CT	action
EOS (# & %)	Granulations modifications	(-)	*Cause:* Toxic or abnormal granules, as much as degranulated areas may alter optical properties of eosinophils and cause an erroneous EOS counting *Indication:* diffuse downwards spreading EOS clump overlapping NEU clump, NH Flag	Seek for Granulations modifications on smear
	Atypical Neutrophils	(+)	*Cause:* hyper-segmented or giant Neutrophils may overlap EOS clump *Indication:* upwards spreading NEU clump overlapping EOS clump, NH &/or IC &/or L5 Flags	Seek atypical Neutrophils on smear
BAS (# & %)	Blasts, immature, atypical cells	(+)	*Cause:* abnormal cells may overlap the basophils clump and interfere with the basophil counting *Indication:* absence of LYM/MON(NEU) gap with RL &/or NL &/or HL flags	Seek for blasts on smear
RBC	Cold Agglutinin	(-)	*Cause:* high IgM level may lower RBC and increase MCV *Indication:* ↑MCV, ↓HCT	Seek for red cell clumping on Smear
	Severe Microcytosis	(-)	*Cause:* in very rare case of severe microcytosis, size of microcytes may fall below the minimum RBC threshold. *Indication:* ↓RBC, ↑Plt R1 &/or P3 flags	Seek for microcytes on Smear
	Macrocytosis	(-)	*Cause :* in case of macrocytosis, size of macrocytes may overcome the maximum RBC counting zone. *Indication :* ↓RBC, ↑MCV, R2 flag	
	RBC agglutination	(?)	*Cause:* agglutinated RBC may cause a low inaccurate RBC count. *Indication*: abnormal MCH and MCHC values	Seek for clumped RBC on Smear
	Fragmented RBC	(-)	*Cause:* RBC fragments (schizocytes) may agglutinate and interfere with RBC counting. *Indication:* ↓RBC, ↑Plt, ↑MPV, P2 flag	Seek for schizocytes on Smear
	Leukocytosis	(+)	*Cause:* high level of WBC may cause an erroneous RBC count. *Indication:* very high WBC (>100,000/µL), ↑RBC , ↑MCHC	Centrifuge the sample and re-assay the re-diluted RBC part.

(+): Instrument count is affected by an increase in the result.
(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or decrease in the result which is sample dependent.

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Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22 CT	action
HGB	Leukocytosis	(+)	*Cause:* high level of WBC causes excessive light scatter that interferes with Hgb measurement. *Indication:* very high WBC (>100,000/µL), ↑MCHC	Centrifuge the sample remove WBC and re-assay the re-diluted RBC part. Or use reference spectrophotometric method
	hyperlipidemia	(+)	*Cause:* in case of high level of lipids in blood will give the plasma a "milky" appearance that causes inaccurate Hgb measurement. *Indication:* plasma appearance ↑MCHC,	Use reference manual methods and a plasma blank to determine Hgb
	Abnormal Protein hyperproteinemia, hyperbilirubinemia	(+)	*Cause:* in case of high level (or abnormal) of proteins in blood will give the lysed sample a "cloudy" appearance that causes inaccurate Hgb measurement. *Indication:* lysed sample appearance ↑MCHC	Use reference manual methods and a plasma blank to determine Hgb
HCT	Cold Agglutinin	(-)	*Cause:* high IgM level may lower RBC and increase MCV *Indication:* ↑MCV, ↓HCT,	Seek for red cell clumping on Smear
	Leukocytosis	(+)	Elevation of WBC	
	Abnormal Red Cell Fragility	(-)	*Cause*: in case of chemotherapy cytotoxic and immunosuppressive drugs may increase RBC as well as WBC fragility leading to a low HCT *Indication:* P1 flag	
	Spherocytosis	(?)	*Cause:* in case of Spherocytosis, sphered RBC are smaller than normal RBC leading to a low HCT *Indication:* ↓MCV, P2 &/or P3&/or R1 flags	Seek for spherocytes on Smear
MCV	RBC agglutination	(?)	*Cause:* agglutinated RBC may cause an inaccurate MCV value. *Indication*: abnormal MCH and MCHC values	Seek for clumped RBC on Smear Use reference manual methods to determine the accurate MCV value.
	Megalocytic Platelets	(-)	*Cause:* may cause a low inaccurate MCV value because of an excessive size *Indication:* ↓Plt ↑MPV , P2 flag	Seek for megalocytic platelets on Smear
	Leukocytosis	(+)	*Cause:* high level of WBC interferes with MCV determination. *Indication:* very high WBC (>100,000/µL) , ↑MCHC	Use reference manual methods to determine the accurate MCV value.

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Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22 CT	action
MCH	See Hgb value and RBC count interferences		*The MCH is determined according to Hgb value and RBC count. The limitations listed for Hgb and RBC may cause indirect interferences.*	
MCHC	See Hgb and HCT values interferences		*The MCMH is determined according to Hgb and HCT values. The limitations listed for Hgb and HCT may cause indirect interferences.*	
RDW	See RBC count interferences	(?)	*The RDW is determined according to RBC count. The limitations listed for RBC may cause indirect interferences.*	
PLT	Platelet Aggregation	(-)	*Cause:* Clumped platelets may cause a decreased platelet count *Indication:* aggregates may be detected on the WBC scattergram with N1 &/or N2 &/or L1 &/or HL flags, ↓Plt ↑MPV	Seek for Platelet aggregates on Smear The specimen should be recollected in sodium citrate anticoagulant and re-assayed
	Severe Microcytosis	(+)	*Cause:* in case of severe microcytosis, microcytes and schizocytes are below the RBC inferior threshold and may be counted with Platelets and cause an erroneously high Plt count *Indication:* ↓RBC, ↑Plt R1 &/or P3 &/or P2 flags	Seek for microcytes on Smear
	Megalocytic Platelets	(-)	*Cause :* may cause a low inaccurate platelet count as these platelets exceed the upper threshold for the platelet parameter and are not counted *Indication :* ↓Plt ↑MPV P2 flag	Seek for megalocytic platelets on Smear
	RBC agglutination	(?)	*Cause:* agglutinated RBC may trap platelets and cause a low inaccurate Plt count. *Indication:* abnormal MCH and MCHC values	Seek for clumped RBC on Smear
	Hemolysis	(+)	*Cause:* hemolysed samples contain RBC stromas that cause a high inaccurate Plt count. *Indication:* abnormal MCH and MCHC values ↓RBC	

(+): Instrument count is affected by an increase in the result.
(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or decrease in the result which is sample dependent.

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5. SAMPLE ANALYSIS

5.1 VERIFICATIONS BEFORE STARTING

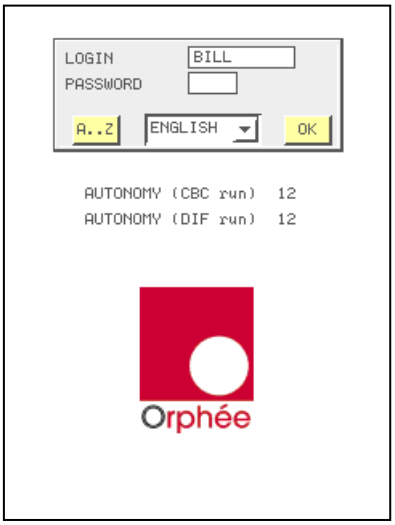
Before starting **MYTHIC 22 CT**, we recommend to check the reagent levels in each bottle, and the level of the waste container. Please also check the paper quantity in the printer.

5.2 START UP

- Press ON/OFF button on the printer to start.
- If needed switch on the power supply (the power supply can stay on).
- Press ON/OFF button on the Mythic.

- The initialization menu is displayed and **MYTHIC 22 CT** performs a home position checking for the three motors.

- The cycle LED turns red. None cycle can be performed before it turns green.



- Enter your login and password as described in section 3.1.

- **AUTONOMY (run)** indicates the number of samples (runs) you can perform in CBC or DIF mode (calculated with the smaller quantity of reagents).

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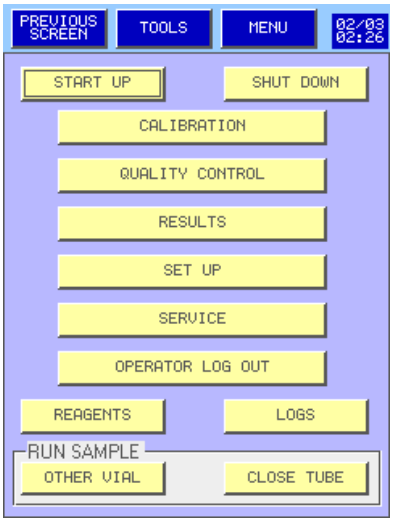
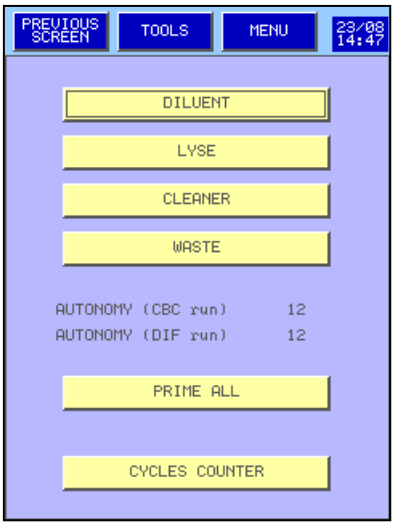
5.3 REAGENT REPLACEMENT

	The reagents must be stored 24 hours minimum at room temperature before use.



- To check the level of each reagent, press



- If one or more reagent needs to be replaced, proceed as indicated in section 1.5.2

- **AUTONOMY (run)** indicates the number of samples (runs) you can perform in CBC or DIF mode (calculated with the smaller quantity of reagents).

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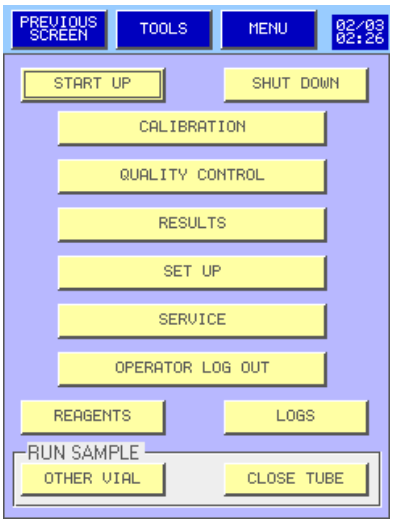
5.4 START UP RINSING



- To rinse the system before analysis, press START UP

- The cycle LED turns red. None cycle can be performed before it turns green.

- Mythic will perform 1 to 3 empty cycles to check the carry over level. This level should not to exceed the following ratios :

  - WBC : 0.5
  - RBC : 0.1
  - HGB : 0.5
  - PLT : 10

If the level is higher, **MYTHIC 22 CT** displays a window "START UP FAILED" press OK and perform a new start up. If the user chooses to run samples, every result will be printed with **"Start Up not done"** message.

5.5 PREPARATIONS BEFORE ANALYSIS

5.5.1 Anticoagulant and mixing

The human blood venous sample must be collected in an EDTA **K2** or **K3** (Ethylene Diamine Tetracetic Acid, two or tri potassic) tube in sufficient quantity. The 5 part diff results are available up to **48 hours** after the blood draw and if the sample is stored at 4 to 8°C.
It must be correctly homogenized before analysis. It is recommended to use a rotary agitator turning between 20 to 30 turns/mn during **10 minutes**.
The results and the number of flags could be affected in case of too much sampling (more than 20 times).

	A volume of insufficient blood for the quantity of anticoagulant or a bad mixing may involve an erroneous result.

5.5.2 Blood sample collection tube

The following table shows the type of sample collection tubes available with the MYTHIC 22 CT.

	The use of another types of sample collection tube could destroy the sampling needle or give false results, please contact your Orphée's representative before to use this other type.

The more important close tube characteristics are the length and diameter for the tube holder, the cap which contains the rubber membrane for the piercing module.
The close tubes serial numbers below are showed only as example, please contact your tube vendor for more details about EDTA and VACCUM contain.
The minimum volume of blood required in the sample tube is **300µl**.

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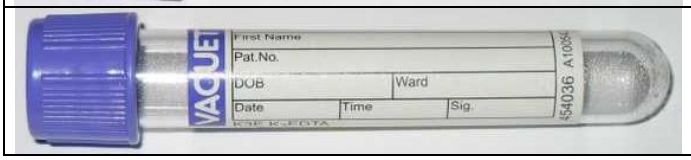
	BD	368861	13x75
	BD	368452	13x75
	BD	367651	13x75
	BD	367652	13x75
	VENOJECT TERUMO		13x75
	VENOSAFE TERUMO	VF054SDK	13x75
	VACUETTE	454036	13x75

5.6 ANALYSIS

5.6.1 Introduction

⚠	**It is recommended (or mandatory according to the legislation) to carry out a Quality Control (QC) and possibly a calibration before any analysis (see section 6 & 7).** **Read the analytical limitations (see section 4.4) before run the sample.**

⚠	**The working temperature of the fluidic part must be reached before starting the analysis.** **The average time to reach it is around 15 min at a room temperature > 23 °C (see 5.6.3).**

If the quality control is not carried out, before beginning the series, it is recommended to perform two analyses on a normal sample of the day before to verify if the results are closed to results obtained the day before.

NOTA: The **MYTHIC 22 CT** is delivered with a standard parameter setting described in section 3.

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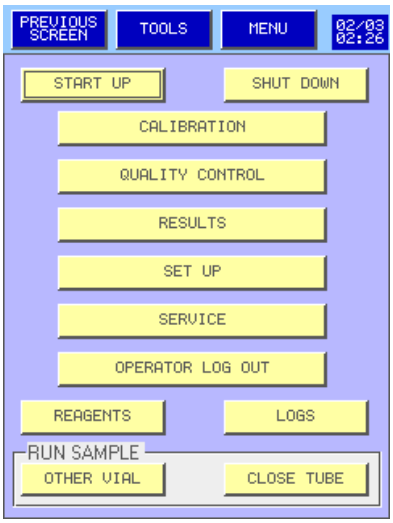
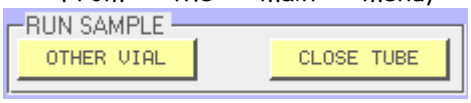
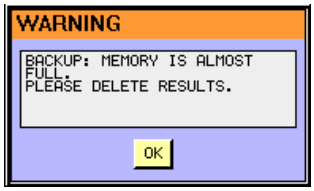
5.6.2 Sample Identification



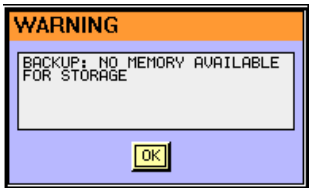
- From the main menu, press the appropriate button



to reach the analysis display.

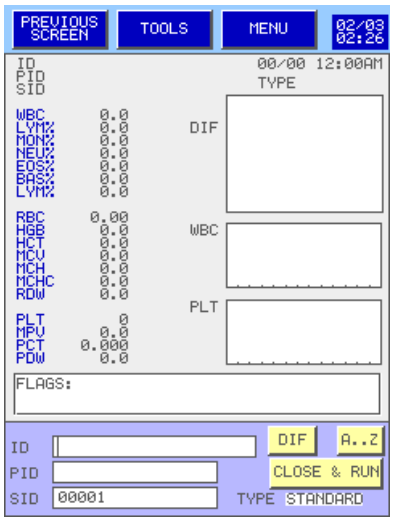


- This prompt appears when the results memory is almost full.



- This prompt appears when the results memory is totally full.

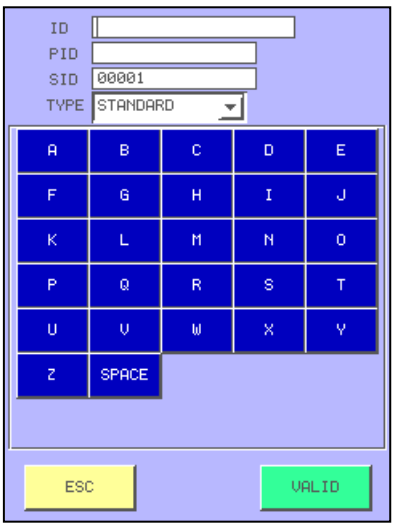
- To delete results see section 5.10



- The display bottom is reserved for the entry of the next sample identification to run.
- Three fields allow the entry of the identification :
  - ID: Patient Name (**20** characters max.)
  - PID: Patient Identification (**16** characters max.)
  - SID: Sample identification (**16** characters max.)

NOTA: SID number is already done. (See section 3.3)

- Press A..Z to accede to the blood type and alphabetic characters.
- Press DIF or CBC to change the measurement mode.
- Press CLOSE & RUN (see section 5.6.3) or OTHER VIAL (see section 5.6.4) to launch the measurement cycle.



IDENTIFICATION PROCEDURE:

- To enter or modify identification, place the cursor in the selected field with your finger or the arrow.
- To enter a figure, use the keyboard on the right of the screen, for a letter use the alphabetic keyboard by pressing A..Z.
- To accede to another character page press << or >>.
- To change the blood type, press the combo box TYPE STANDARD and select the type
- To valid the entry and return to the previous screen, press VALID.
- To return to the previous screen without validation, press ESC.

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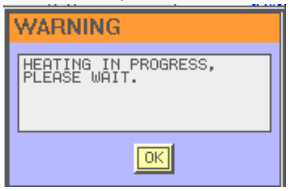
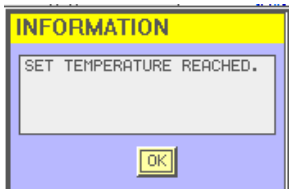
NOTA: The needle will be available as soon as the working temperature is reached (about 15 min at 23°C of room temperature).



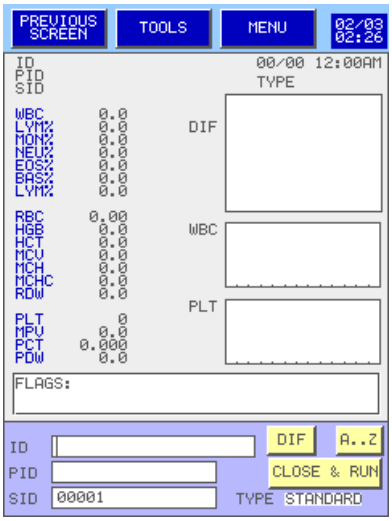
This prompt means that the temperature setting of the enclosure and/or the reagent is not reached yet.



This prompt means that the temperature setting of the enclosure and/or the reagent is reached and that a cycle can be run.

5.6.3 Close tube sample run

Wear rubber gloves and wash hands with a disinfectant after completion of work.

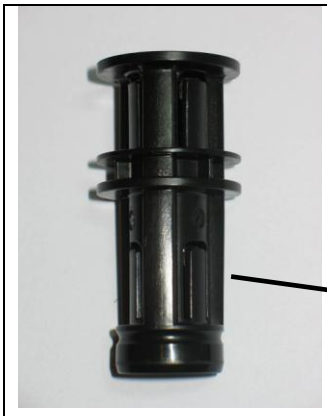


As soon as the temperature is reached, a measurement cycle can be run :

- From the MAIN MENU, press CLOSE TUBE to accede to the closed tube measurement screen.
- The tube holder door open.
- Use the appropriate tube holder.

Never use a tube holder with a non dedicated sample tube, the needle could be destroyed and the results could be erroneous (See the authorized tubes in section 5.5.2).

- If no tube holder exist for a special vial, please refer to the section 5.6.4 to run it.



Tube holder

Tube holder door support

Put the sample tube inside the tube holder

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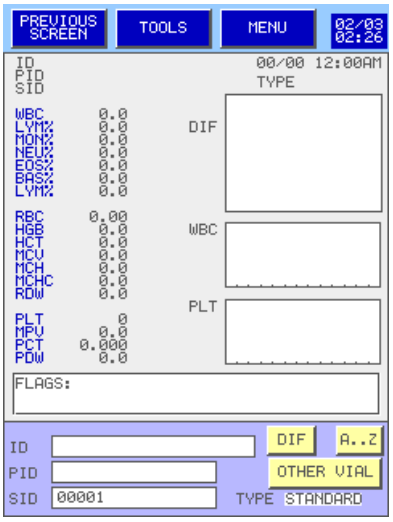
- To launch the measurement cycle, push slowly the door which close itself or press CLOSE & RUN on the screen.

	It is mandatory to change for a new cap after a Maximum of 10 piercing.

- To open the door press OPEN or wait the automatic opening at the end of the measurement cycle.

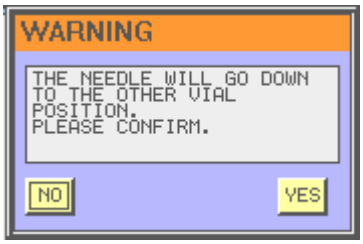
5.6.4 Other vials sample run

	Wear rubber gloves and wash hands with a disinfectant after completion of work.



As soon as the temperature is reached, a measurement cycle can be run :

- From the MAIN MENU, press OTHER VIAL to access to the other vial measurement screen.
- The following prompt appears:



- Press YES to allow the down of the needle if not press NO.

- Present the tube of the blood sample under the needle and press RUN SAMPLE on the display.

- The cycle LED located at the top of the needle becomes red the tube can be removed only when the needle up.
- A new cycle can be started again when it turns by again green.
- As soon as the cycle is launched, the SID is incremented automatically and, thanks to its data processing multitasks, the **MYTHIC 22 CT** is available for the identification of the following sample (See section 5.6.2).

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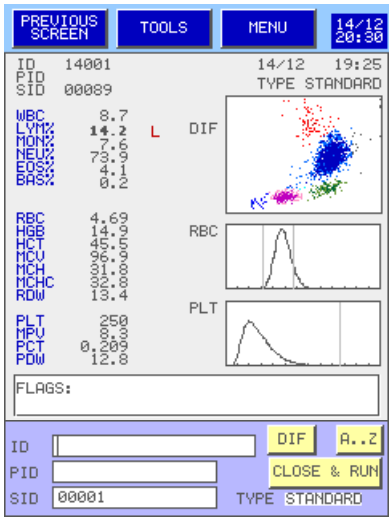
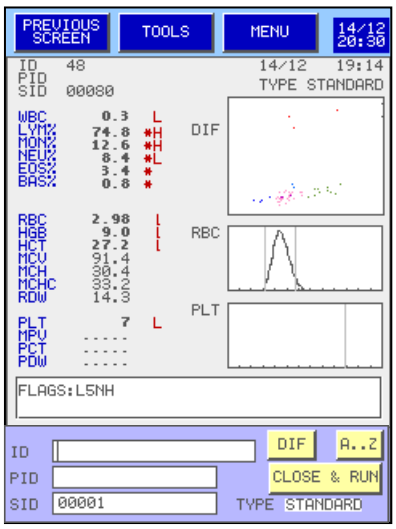
5.7 RESULTS



- The results of the analysis are sent before the cycle is finished (to be checked) at the same time as the printer starts.

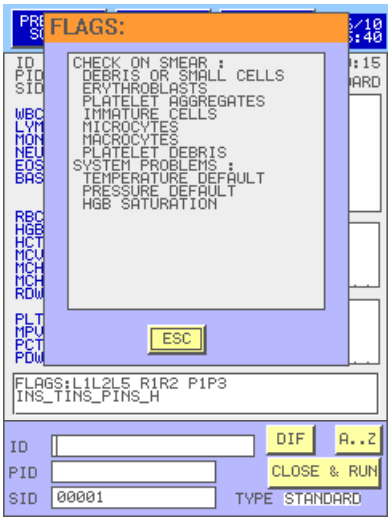
NOTA: It is not necessary to wait for the end of the result printing to launch a new analysis.

- The results are sent to the selected unit (See section 3).
- The information located on the right of each parameter corresponds to the indicators for out of range limits and for the rejections (see section 3).
- The scattergram and curves of distribution of each cellular population are located on the right screen.
- Under the results a zone (FLAGS) is reserved for analytical alarms (see section 8.5).). Press in this zone to have a clear explanation of the flags.
- At the bottom of the screen, there are the three inlet fields for the identification of the next sample. (See section 5.6.2).



- Example of an abnormal result analysis in **DIF** mode with flags located at the right of the results and in the flag box under the result.

	It is mandatory to read the section 8.5 to understand the flags meaning.



- Press on the flags zone to open the flags window.

- In regard of the different flags found by the MYTHIC 22CT the upper part propose list of the cells to check on the smear.

	In any case this proposal is a commitment, it is mandatory to read the section 8.5 to understand the flags meaning.

- The lower part describe the machine problem (see section 8.5.2).

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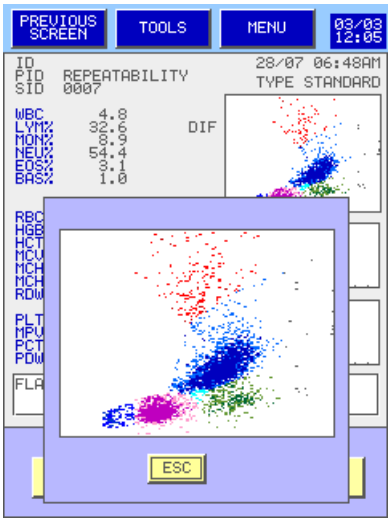
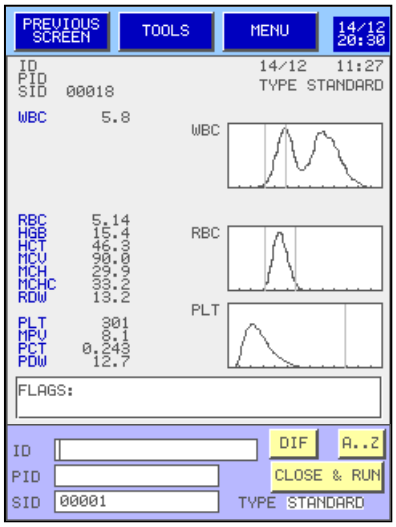
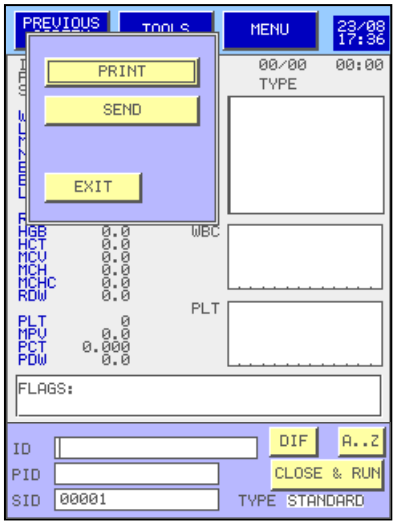


- Press on the scattergram to access to a zoomed view.



- Example of a normal result analysis in **CBC** mode.



- Press TOOLS to reprint or to resend the result.

- To print the result press PRINT.
- To send the result, press SEND.
- To close the window, press EXIT.

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5.8 PRINTING

Once the analysis is finished, the **MYTHIC 22 CT** prints a result report. To modify the printing presentation or to disconnect the printer see section **3.4.1**.
To load a new printer driver see section **3.3**.

5.8.1 Model report (A4) – external printer

EPSON LX 300+ model

One result per page

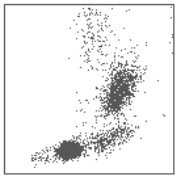
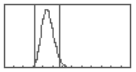
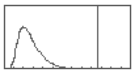
DIF mode

ORPHEE-MEDICAL
Presentation Results MYTHIC 22

Name :
Comments :
Patient Id :
Sample Id : 00017
Type : STANDARD

Operator ID : SAS Date : 14/12/2005 11:25:56 Seq# : 00032

	Result	Flags	Unit	Normal limits
WBC	5.7		10^3/l	4.0 / 12.0
LYM%	40.2		%	25.0 / 50.0
MON%	**11.3**	h	%	2.0 / 10.0
NEU%	**42.8**	L	%	50.0 / 80.0
EOS%	5.0		%	0.0 / 5.0
BAS%	0.7		%	0.0 / 2.0
LYM	2.3		10^3/l	1.0 / 5.0
MON	0.6		10^3/l	0.1 / 1.0
NEU	2.4		10^3/l	2.0 / 8.0
EOS	0.3		10^6/l	0.0 / 0.4
BAS	0.0		10^6/l	0.0 / 0.2
RBC	5.12		10^6/l	4.00 / 6.20
HGB	15.3		g/dl	11.0 / 17.0
HCT	46.4		%	35.0 / 55.0
MCV	90.6		m^3	80.0 / 100.0
MCH	30.0		pg	26.0 / 34.0
MCHC	33.1		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	308		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.248		%	0.200 / 0.500
PDW	12.0		%	10.0 / 18.0

FLAGS:

MONOCYTOSIS NEUTROPENIA

Comments :

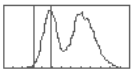
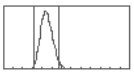
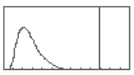
CBC mode

ORPHEE-MEDICAL
Presentation Results MYTHIC 22

Name :
Comments :
Patient Id :
Sample Id : 00018
Type : STANDARD

Operator ID : SAS Date : 14/12/2005 11:27:30 Seq# : 00033

	Result	Flags	Unit	Normal limits
WBC	5.8		10^3/l	4.0 / 12.0
RBC	5.14		10^6/l	4.00 / 6.20
HGB	15.4		g/dl	11.0 / 17.0
HCT	46.3		%	35.0 / 55.0
MCV	90.0		m^3	80.0 / 100.0
MCH	29.9		pg	26.0 / 34.0
MCHC	33.2		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	301		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.243		%	0.200 / 0.500
PDW	12.7		%	10.0 / 18.0

FLAGS:

Comments :

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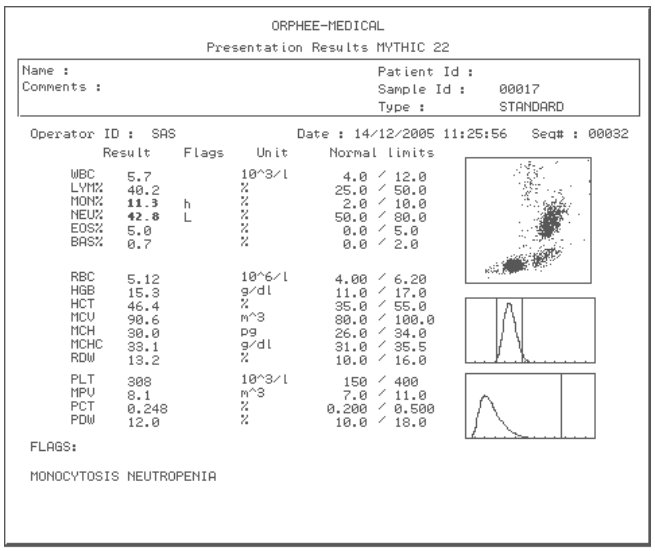
Two results per page

DIF mode



ORPHEE-MEDICAL
Presentation Results MYTHIC 22

Name :
Comments :
Patient Id :
Sample Id : 00017
Type : STANDARD

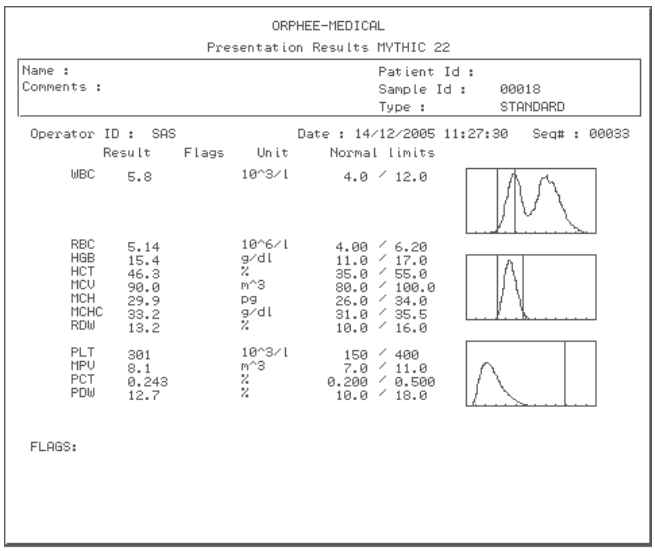
Operator ID : SAS Date : 14/12/2005 11:25:56 Seq# : 00032

	Result	Flags	Unit	Normal limits
WBC	5.7		10^3/l	4.0 / 12.0
LYM%	40.2		%	25.0 / 50.0
MON%	**11.3**	h	%	2.0 / 10.0
NEU%	**42.8**	L	%	50.0 / 80.0
EOS%	5.0		%	0.0 / 5.0
BAS%	0.7		%	0.0 / 2.0
RBC	5.12		10^6/l	4.00 / 6.20
HGB	15.3		g/dl	11.0 / 17.0
HCT	46.4		%	35.0 / 55.0
MCV	90.6		m^3	80.0 / 100.0
MCH	30.0		pg	26.0 / 34.0
MCHC	33.1		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	308		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.248		%	0.200 / 0.500
PDW	12.0		%	10.0 / 18.0

FLAGS:

MONOCYTOSIS NEUTROPENIA

CBC mode



ORPHEE-MEDICAL
Presentation Results MYTHIC 22

Name :
Comments :
Patient Id :
Sample Id : 00018
Type : STANDARD

Operator ID : SAS Date : 14/12/2005 11:27:30 Seq# : 00033

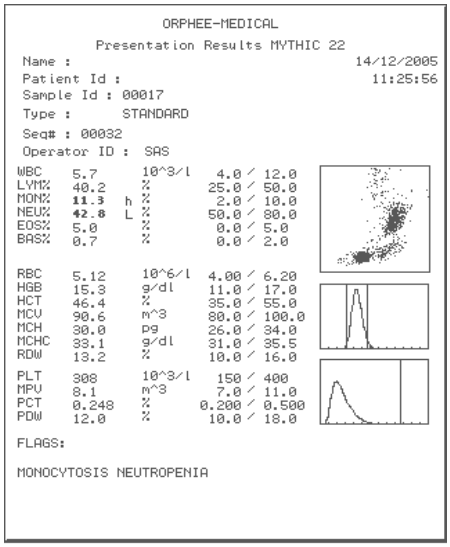
	Result	Flags	Unit	Normal limits
WBC	5.8		10^3/l	4.0 / 12.0
RBC	5.14		10^6/l	4.00 / 6.20
HGB	15.4		g/dl	11.0 / 17.0
HCT	46.3		%	35.0 / 55.0
MCV	90.0		m^3	80.0 / 100.0
MCH	29.9		pg	26.0 / 34.0
MCHC	33.2		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	301		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.243		%	0.200 / 0.500
PDW	12.7		%	10.0 / 18.0

FLAGS:

5.8.2 Model report – Thermal printer

SEIKO DPU 414 model

DIF mode



ORPHEE-MEDICAL
Presentation Results MYTHIC 22

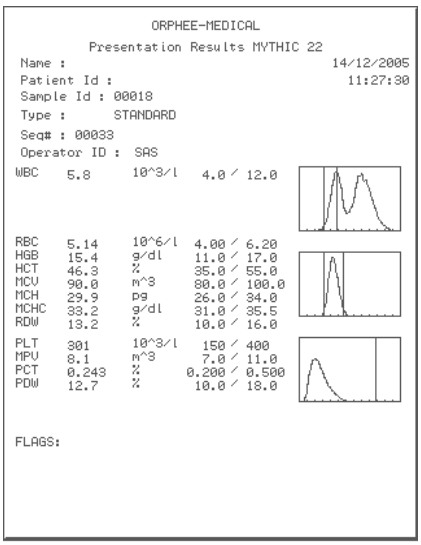
Name : 14/12/2005
Patient Id : 11:25:56
Sample Id : 00017
Type : STANDARD
Seq# : 00032
Operator ID : SAS

WBC	5.7		10^3/l	4.0 / 12.0
LYM%	40.2		%	25.0 / 50.0
MON%	**11.3**	h	%	2.0 / 10.0
NEU%	**42.8**	L	%	50.0 / 80.0
EOS%	5.0		%	0.0 / 5.0
BAS%	0.7		%	0.0 / 2.0
RBC	5.12		10^6/l	4.00 / 6.20
HGB	15.3		g/dl	11.0 / 17.0
HCT	46.4		%	35.0 / 55.0
MCV	90.6		m^3	80.0 / 100.0
MCH	30.0		pg	26.0 / 34.0
MCHC	33.1		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	308		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.248		%	0.200 / 0.500
PDW	12.0		%	10.0 / 18.0

FLAGS:

MONOCYTOSIS NEUTROPENIA

CBC mode



ORPHEE-MEDICAL
Presentation Results MYTHIC 22

Name : 14/12/2005
Patient Id : 11:27:30
Sample Id : 00018
Type : STANDARD
Seq# : 00033
Operator ID : SAS

WBC	5.8		10^3/l	4.0 / 12.0
RBC	5.14		10^6/l	4.00 / 6.20
HGB	15.4		g/dl	11.0 / 17.0
HCT	46.3		%	35.0 / 55.0
MCV	90.0		m^3	80.0 / 100.0
MCH	29.9		pg	26.0 / 34.0
MCHC	33.2		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	301		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.243		%	0.200 / 0.500
PDW	12.7		%	10.0 / 18.0

FLAGS:

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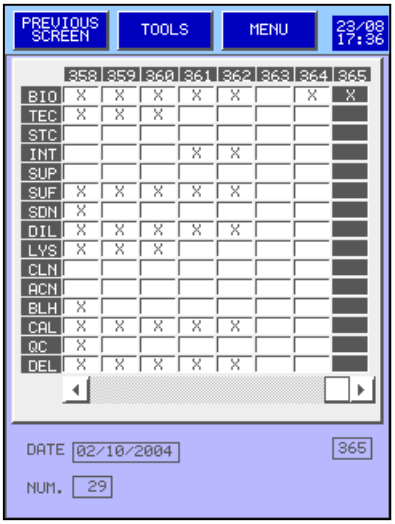
5.9 LOGS

From the main menu, press LOGS to reach the logs display



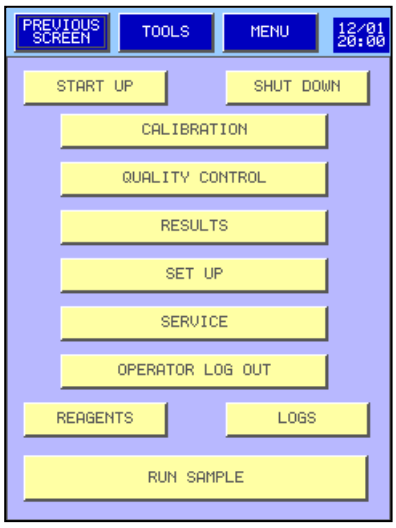
- **MYTHIC 22 CT** manage a simplified log allowing to save and display all the events done for the following actions:
  - **BIO**: Login with the Biologist password.
  - **TEC**: Login with the service Technician password.
  - **STC**: Login with the "Super" service Technician password.
  - **INT**: An intervention or maintenance has been performed.
  - **SUP**: Start Up cycle has been performed.
  - **SUF**: Start Up cycle has failed.
  - **SDN**: Shut down cycle has been performed.
  - **DIL**: Diluent replacement.
  - **LYS**: Lysis replacement.
  - **CLN**: Cleaner replacement.
  - **ACN**: Autocleann cycle.
  - **BLH**: Bleach cycle.
  - **CAL**: Calibration.
  - **QC**: Quality control.
  - **DEL**: Results deleted in Archive.

Each column is identified by a number (recall at the right bottom of the screen 365). In the bottom of the screen is displayed the date DATE 02/10/2004 and under it the number of analysis NUM. 29 run during this day.

- To print or save the log report press TOOLS
- Select ALL to print or save the logs of the number of pages indicated on the screen.
- To print or save the logs of one or more days select DAY then enter the day reference number.

Press SAVE to save the logs on the USB thumb drive.

5.10 ARCHIVE



MYTHIC 22 CT can save more than the last 1500 patients with results, alarms, distribution curves in the internal memory and until a maximum of 60 000 results in a memory stick (USB key) of 512 Mbit or more (see section 3.4.7).

- Press RESULTS to enter the archive display.

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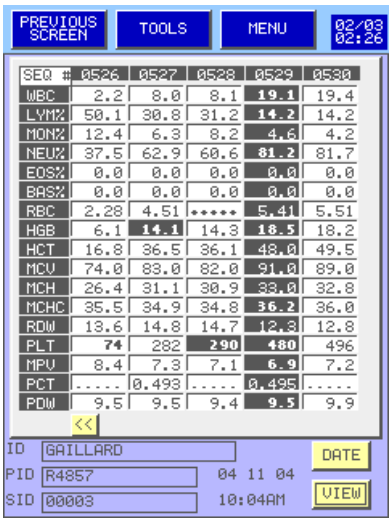
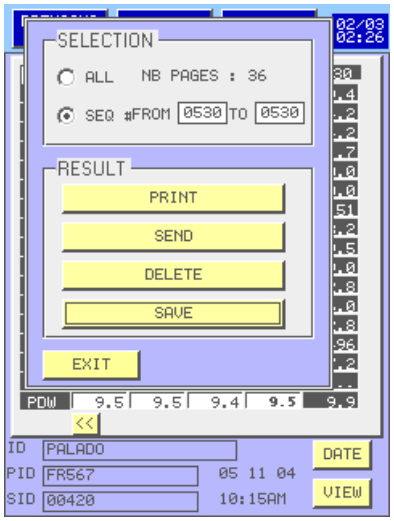
5.10.1 Results

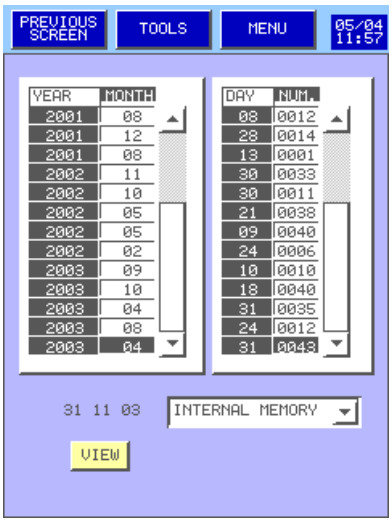


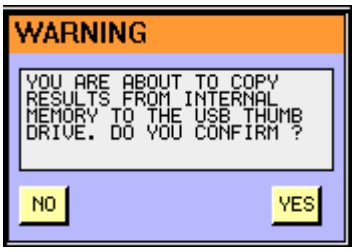
- The Archive display allows to view the results of the analysis.
- Each result is saved in a worklist of the day.
- The first column presents the name of the different parameters, the first line the result number.
- The results of the patients are presented in column.
- At the bottom of the display, under the table, the **ID**, **PID**, **SID**, **SEQ** number, date and time of the selected patient (dark background) are presented for each result selected.
- The button << >> , located under the table, allows to change pages.
- To find a result in the list, select the **SEQ** number wanted, press RES
- To view an entire result, select the **SEQ** number wanted, press VIEW
- To print, send, delete or save (in an USB key) results press TOOLS
- DATE allows to accede to the results date list.



- It is possible to print, send, delete or save in a USB key :
  - . All results : Press ALL
  - . NB PAGES : 36 for printing.
  - . Selected results : Select the first and the last results:
    SEQ #FROM 0530 TO 0530
- Then press on PRINT SEND DELETE or SAVE

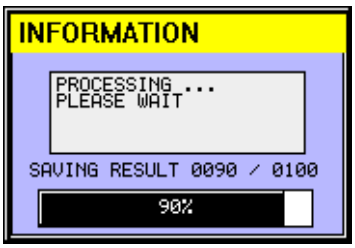
NOTA : the printed report is a **list** of all selected patients.





- This prompt appears to confirm the storage in the USB key.

	If you press YES the selected results will be deleted from the internal memory and stored in the USB key.



- This prompt allows to follow the storage.

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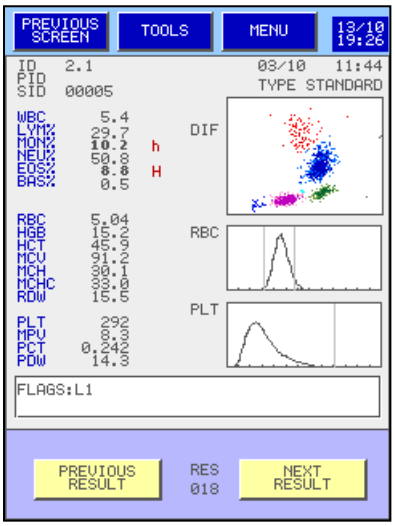
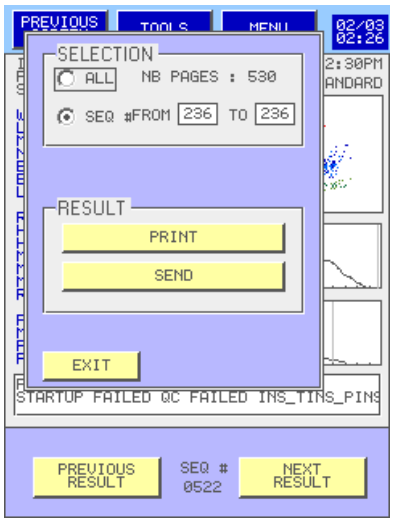
5.10.2 View

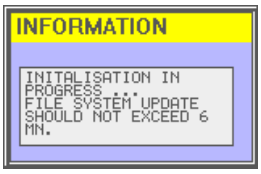


- Keys PREVIOUS RESULT and NEXT RESULT allow to display each result and its identification.
- To print, send or delete a result, press TOOLS
- The effects of the **TOOLS** key are as described in section 5.10.1.
- The printed report is full page with one or two results per page.

- To come back to the archive main page, press PREVIOUS SCREEN.
- To come back to the Main Menu press MENU.



- It is possible to print or send:
  - . All results : Press ALL
  - . NB PAGES : 36 for printing.
  - . Selected results : Select the first and the last results:
    SEQ #FROM 0530 TO 0530
- Then press on PRINT or SEND



This message appears when you exit the result screens and it could stay up to 6 mn to enable the update of all the files.

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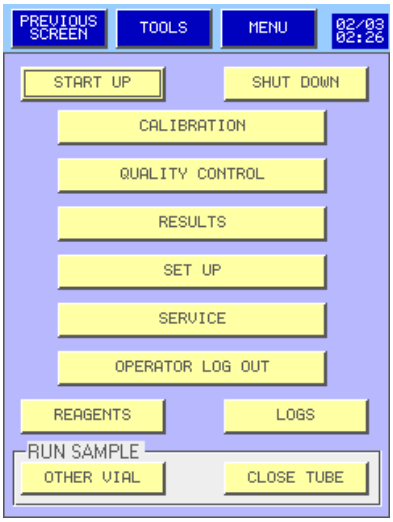
5.11 STAND BY AND SHUT DOWN



- From the main menu, press SHUT DOWN. **MYTHIC 22 CT** automatically performs a shut down cycle.
- All the hydraulic circuits are rinsed, then cleaned with the cleaning solution.
- At the end of the cycle, **MYTHIC 22 CT** automatically stops.
- Shut Down can be automatically performed after a setting time (see section 3.4.6)

NOTA : After a shut down, it is impossible to perform an analytical cycle without launching a start up cycle. (see section 5.2)

MYTHIC 22 CT must stay at rest with cleaning solution during three hours every 24 hours.

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6. QUALITY CONTROL

6.1 INTRODUCTION

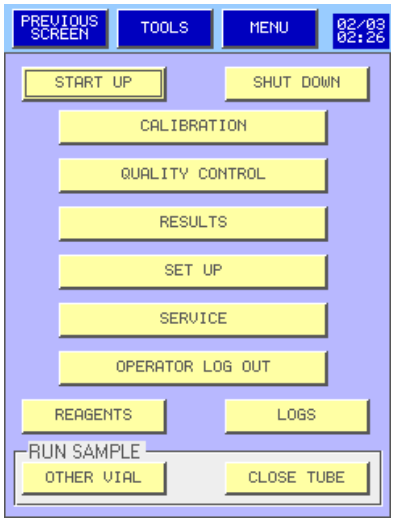
Quality control allows checking the stability of the **MYTHIC 22 CT** analytical performances when operating.
Orphée recommends to use the following controls:
- **Myt-5D** tri level code number MYT502
- **Myt-5D** Normal level code number MYT506

	The control blood must be used before its expiry date and stored according to the manufacturer instructions for use. It must be well-mixed before use according with the instruction for use..

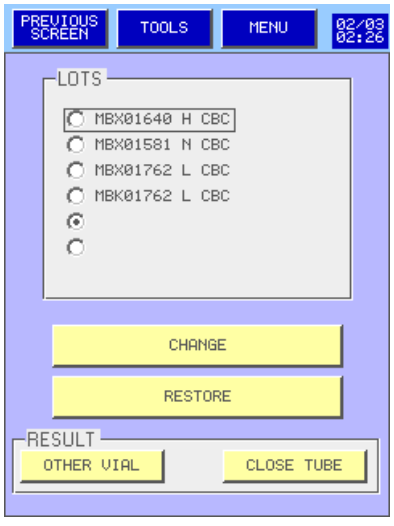
In case of no local regulation, it is recommended to run a control blood at the beginning of each working day before running sample.
In case of exceeding the tolerances indicated on the blood control result sheet, it is recommended to perform a calibration (see section 7).

6.2 QC

MYTHIC 22 CT stores in memory up to 100 results per lot for 6 different lots. Results of each lot can be viewed in tables and Levey-Jennings graph.



- Press QUALITY CONTROL to have access to the quality control menu.



- Quality control display presents the identification of the lots.
- The last active lot is labeled with a dark dot on the left lot.
- To choose another lot, press on the wished lot.
- The key CHANGE allows the modification of the identification and the target values.
- The key RESTORE allows to restore the data from a USB key.
- The key OTHER VIAL or CLOSE TUBE allows :
  . To view the result table.
  . To perform quality control analysis.
- To print or send the targets, results and graphics press TOOLS .

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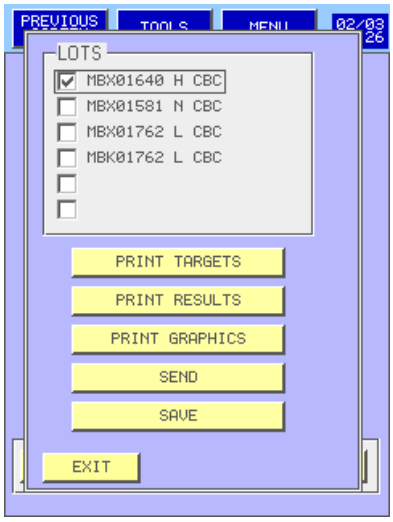
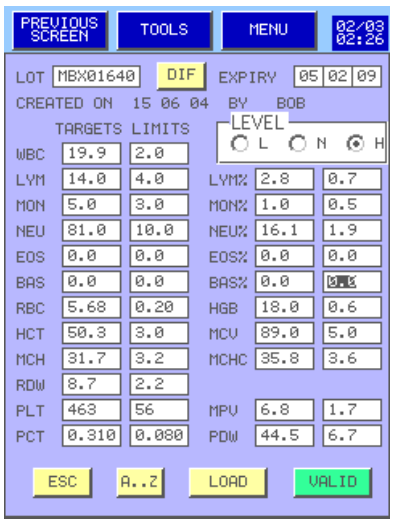


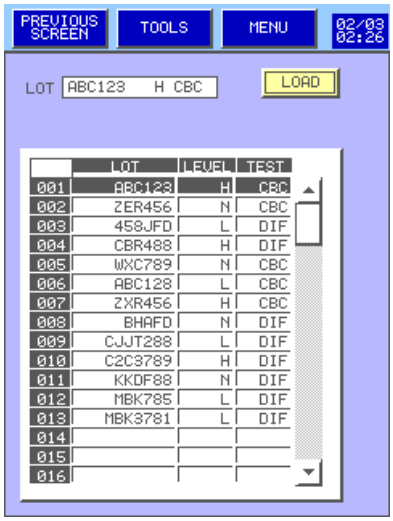
- Tag the lot number to select then press the appropriate button.

- SAVE allows to save the targets, results and graphics in the USB key.

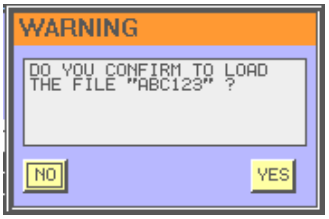
6.2.1 Change



- In this display, the user can enter the :
  - Lot number
  - Expiry date
  - Target values and tolerances
  - Level
- Press DIF to change the analysis mode to CBC or DIF.
- Press ESC to delete the modifications you made.
- Press VALID to validate your modifications or the loading.
- Press A..Z to change the Lot number.
- To print the targets and limits come back to the previous display.
- Press LOAD to load the target and tolerances values, the lot number and expiry date from a USB key.



- Select the right lot then press LOAD



- Press YES to confirm.

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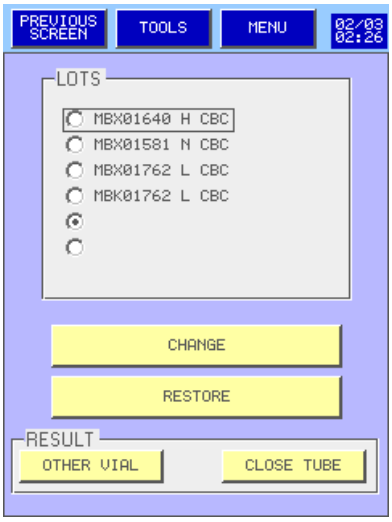
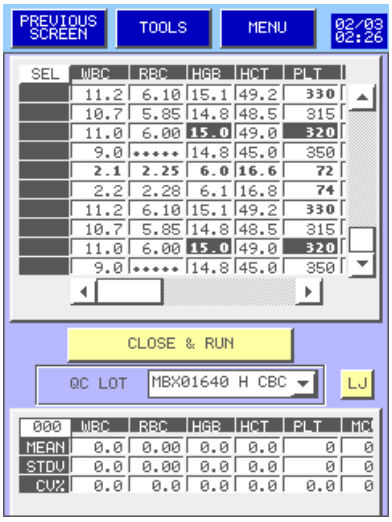
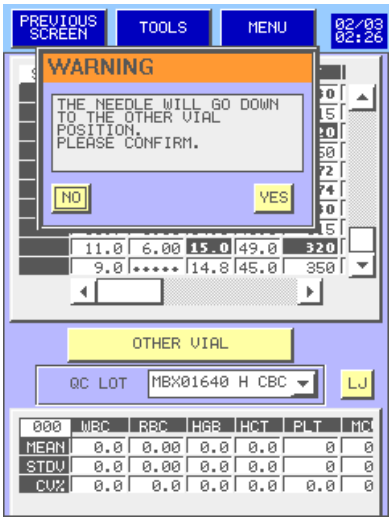
6.2.2 Run control blood



- Select OTHER VIAL or CLOSE TUBE to run the appropriate control blood.


PREVIOUS SCREEN
TOOLS
MENU
02/03 02:26
SEL WBC RBC HGB HCT PLT
CLOSE & RUN
QC LOT MBX01640 H CBC
LJ
000 WBC RBC HGB HCT PLT MC
MEAN 0.0 0.00 0.0 0.0 0 0
STDV 0.0 0.00 0.0 0.0 0 0
CV% 0.0 0.0 0.0 0.0 0.0 0

- To run quality control analysis from a closed vial control blood :
  - Put the control blood in the tube holder.
  - Press CLOSE & RUN.
- Repeat this operation as long as needed.
- The results are displayed in line run after run.
- The statistic calculation are shown at the bottom of the display and are automatically done after each run.
- The cursor allows to display results for the other parameters
- The window QC LOT MBX01 H CBC allows access to the results in memory for another blood control lot.
- The column SEL allows to validate or to unselect a result.



- To run quality control analysis from a open vial control blood :
  - The warning window inform that the needle is going to down in front of the front panel.
  - Press YES then the needle down in front of the tube holder door.
  - Open the vial and enter the needle.
  - Then press RUN SAMPLE to launch the measurement cycle.
- Repeat this operation as long as needed.
- The results are displayed in line run after run.
- The statistic calculation are shown at the bottom of the display and are automatically done after each run.
- The cursor allows to display results for the other parameters
- The window QC LOT MBX01 H CBC allows access to the results in memory for another blood control lot.
- The column SEL allows to validate or to unselect a result.

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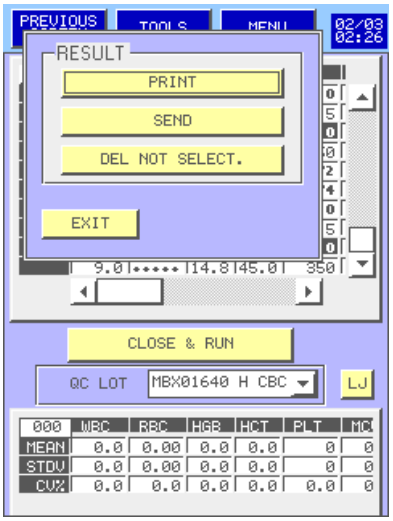
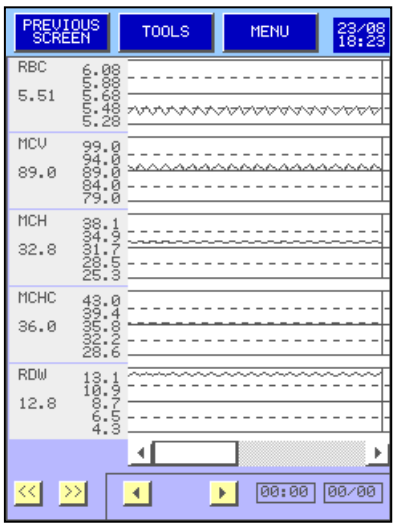


- To print, send or delete a result, press TOOLS

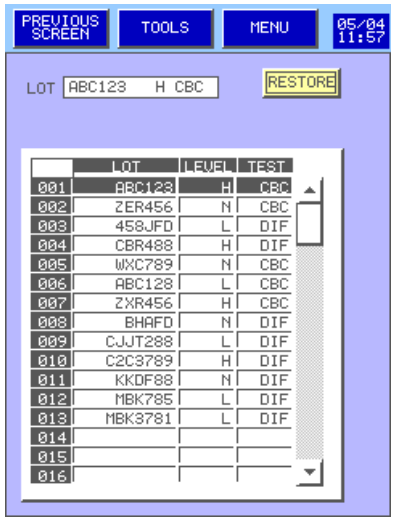
- Press LJ to open the Levey-Jennings graph screen.

6.2.3 Levey-Jennings graph

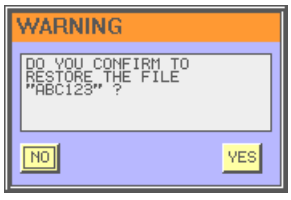


- This menu enables to display the Levey-Jennings graph for each quality control run.
- The column on the left shows each parameter with the target values and the limits. The value under the name of the parameter is the value where the cursor is located on the graph.
- The keys << and >> enable to display the other results.
- The cursor located under the graph enables to display all the registered results.
- The keys 076 enable to move the cursor, the number is the number of the result
- 00:00 00/00 give the date and the time of the displayed result.

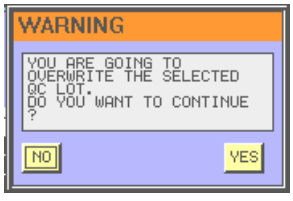
6.2.4 Restore



- This menu enables to restore all the information (results and targets) for the file selected from the USB key to the internal memory.



- Press YES if you are sure to load the selected file.



	All the information of the selected file will be overwrite by the one from the USB key.

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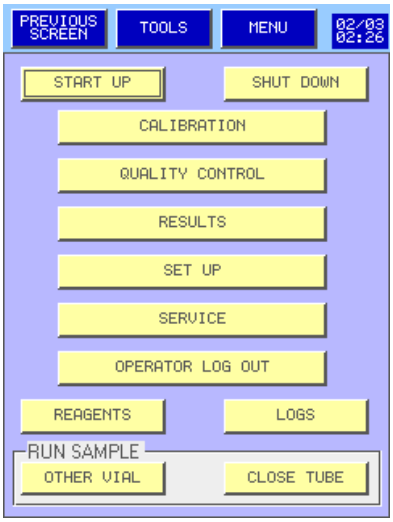
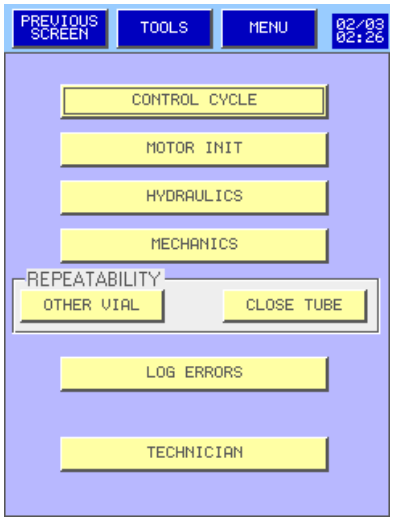
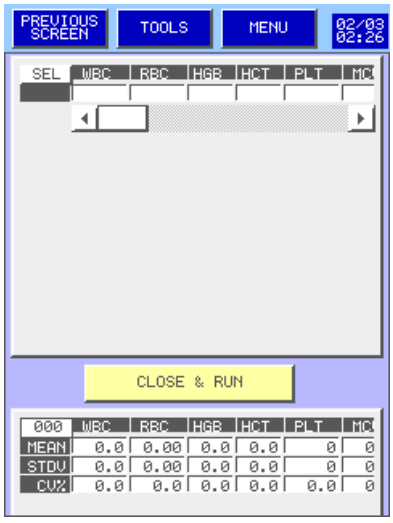
6.3 REPEATABILITY



- To run repeatability, press first SERVICE



- The key OTHER VIAL or CLOSE TUBE allows to access to the repeatability display.



This screen allows to carry out a test of repeatability on all the parameters measured by the **MYTHIC 22 CT**.

- To run repeatability analysis from a closed tube:
  - Put the sample in the tube holder.
  - Press CLOSE & RUN.
- Repeat this operation as long as needed.
- The results are displayed in line run after each run.
- The statistic calculation is shown at the bottom of the display and are automatically done after each run.
- Repeat the operation as many times as desired (maximum **20** runs).

	It is mandatory to change for a new cap after a Maximum of 10 piercing.

- The column SEL allows to validate or to unselect a result.

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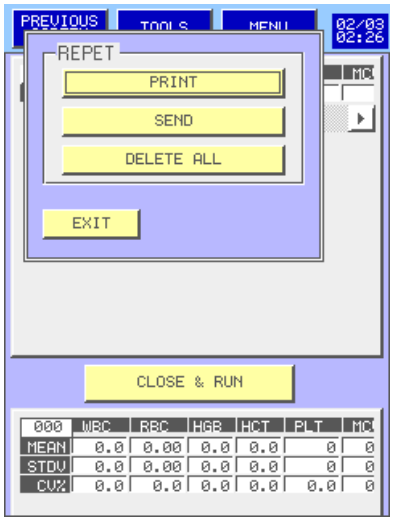

- The key TOOLS allows to do the following actions :
  - o Print the table.
  - o Send the results.
  - o Delete the results.

NOTA : Use the same procedure to run the repeatability with an open vial.

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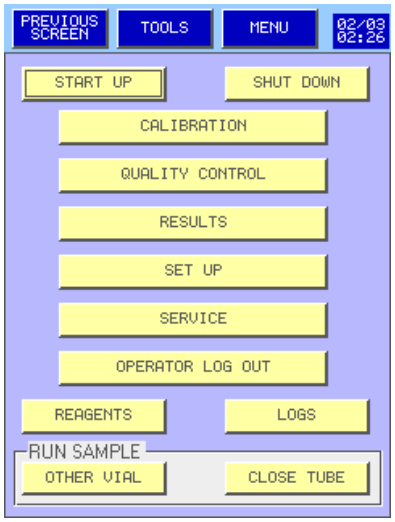
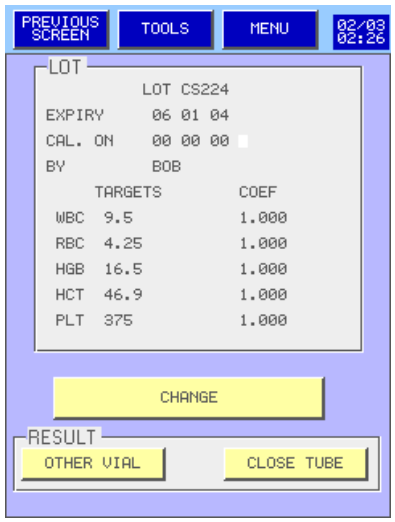
7. CALIBRATION

	The calibration of the MYTHIC 22 CT should be carried out only if the QC carried out on a blood control used under the recommended conditions, is out of the limits to a significant degree (see section 6).

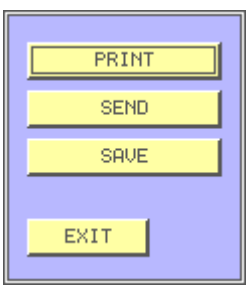
	The calibration blood must be used before its expiry date, be mixed and stored in according with the instructions of use recommended by the manufacturer.



- To reach the screen Calibration, press the key CALIBRATION from the main menu.



- This menu sends the following information :
  - Lot number of the last used calibrator.
  - The expiry date of the current lot.
  - The last date of calibration.
  - The operator name.
  - The target values.
  - The current coefficients of calibration.
- To enter new values or to modify the values, press CHANGE.
- To calibrate, press OTHER VIAL or CLOSE TUBE.
- Press TOOLS then



PRINT, to print these information (see the print out report above).

SEND, to send these information.

SAVE to store these information in the USB key.

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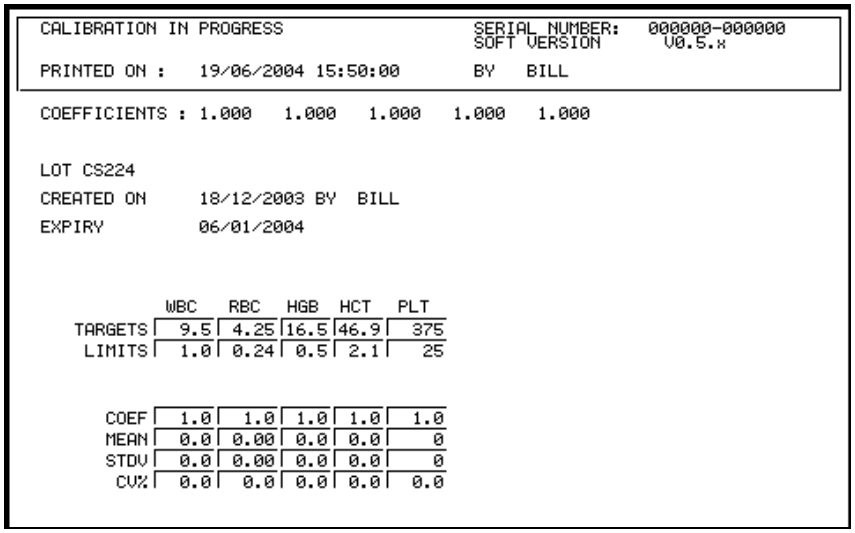
NOTA : If the **M** letter appears on the right of the date of calibration, that means that the last calibration was done by manual modification of the calibration factor (see section 3.4.5)

Model of print out calibration report :



CALIBRATION IN PROGRESS — SERIAL NUMBER: 000000-000000 — SOFT VERSION V0.5.x

PRINTED ON : 19/06/2004 15:50:00 BY BILL

COEFFICIENTS : 1.000 1.000 1.000 1.000 1.000

LOT CS224

CREATED ON 18/12/2003 BY BILL

EXPIRY 06/01/2004

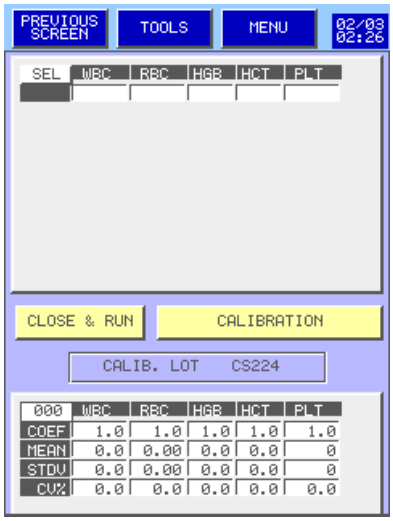
	WBC	RBC	HGB	HCT	PLT
TARGETS	9.5	4.25	16.5	46.9	375
LIMITS	1.0	0.24	0.5	2.1	25

COEF	1.0	1.0	1.0	1.0	1.0
MEAN	0.0	0.00	0.0	0.0	0
STDV	0.0	0.00	0.0	0.0	0
CV%	0.0	0.0	0.0	0.0	0.0

7.1 RUN CALIBRATOR

7.1.1 Calibration blood analysis

This screen allows to run analysis on calibration blood to perform the **MYTHIC 22 CT** calibration.



- To run calibration analysis from a closed vial calibrator blood :
  - Put the control blood in the tube holder.
  - Press CLOSE & RUN.
- The results are progressively sent on line in the table.
- Repeat the operation as many times as desired (maximum **10** runs).
- Statistical calculations are automatically done after each run.
- The window CALIB. LOT CS224 located between the results and the statistical calculation reminds the lot number of the calibrator.
- The column SEL allows to validate or to unselect a result.
- To calibrate press CALIBRATION or TOOLS.

NOTA : Press OTHER VIAL and use the same procedure to run the calibrator open.

NOTA: The results of the analyses performed on one calibrator during the same day remain in the memory and are used in calculations if they are selected.

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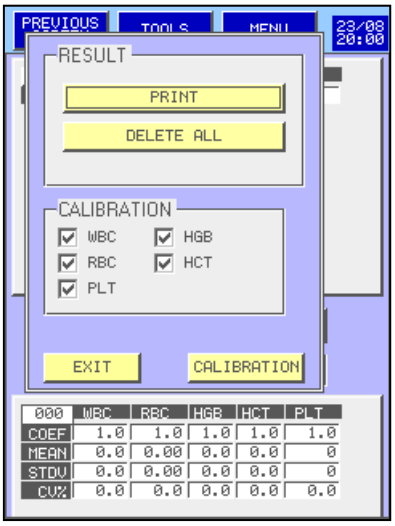
7.1.2 Calibration

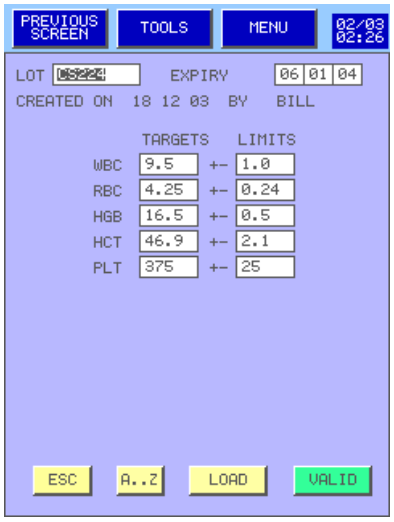
	Before to start the calibration, unselect the results you do not wish to use for the calculation of the calibration (See below section 7.1.1).



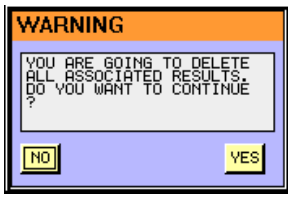
- The key CALIBRATION or TOOLS allows :
  - To calibrate with the selected results.
  - To delete the results. Press DELETE ALL
  - To print the results. Press PRINT (see below the print report)

- To calibrate one or more parameters :
  - Select the parameter
  - Press the key CALIBRATION

7.2 TARGET VALUE MODIFICATIONS



- To modify information relative to a batch or to create a new batch, please follow the following steps :
  - From **Calibration Menu**, press CHANGE.
  - Select the lot number LOT CS224
  - To modify the lot number press A..Z
  - Select the field to be modified.
  - Enter your new value with the numerical keyboard or with the alphabetical keyboard.
  - Press VALID to validate your modifications or the loading.
  - Press ESC to leave the menu without modification.
  - Press LOAD to load the target and tolerances values and expiry date and lot number from a USB key.



	Any modification (lot number, date or target values) involves the deletion of all the associated results always in memory.

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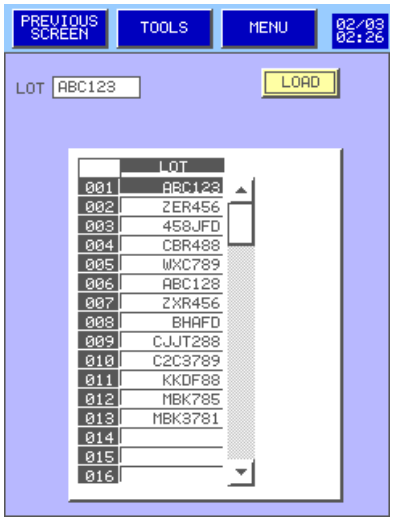
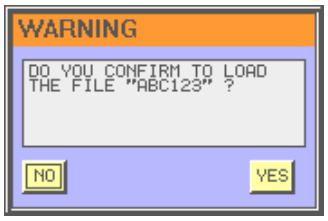


- Plug the USB key then

- Select the right lot then press LOAD.



Press YES to confirm the loading of the target and tolerances values and expiry date and lot number.

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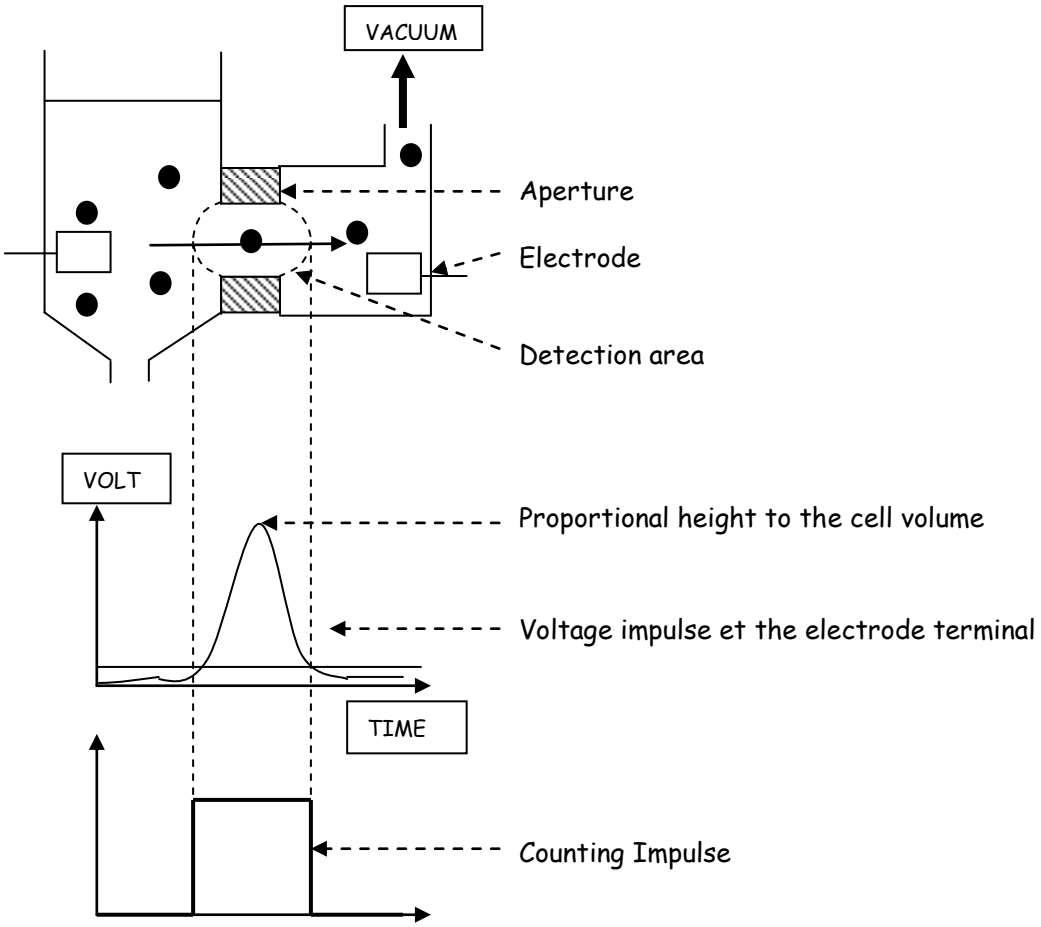
8. TECHNOLOGY

The innovative technology of the **MYTHIC 22 CT** is covered by **six** pending patents. A new innovative concept of optical measurement system and an unique lysing reagent were developed to obtain a so small and powerful analyzer.

8.1 DETECTION PRINCIPLE

8.1.1 WBC, RBC, PLT Counting

The counting of the cellular elements in a blood sample is done with the impedancemetry technique.
This technique is based on the modification of the impedance of a calibrated aperture soaking in an electrolyte and going through a constant course delivered by two electrodes located on both sides of the aperture.
A vacuum applied on a side of the aperture allows the cells passage. They oppose their physical volume to the course passage. A voltage impulse is registered at the electrodes terminal. The height of this impulse is proportional to the cell volume.



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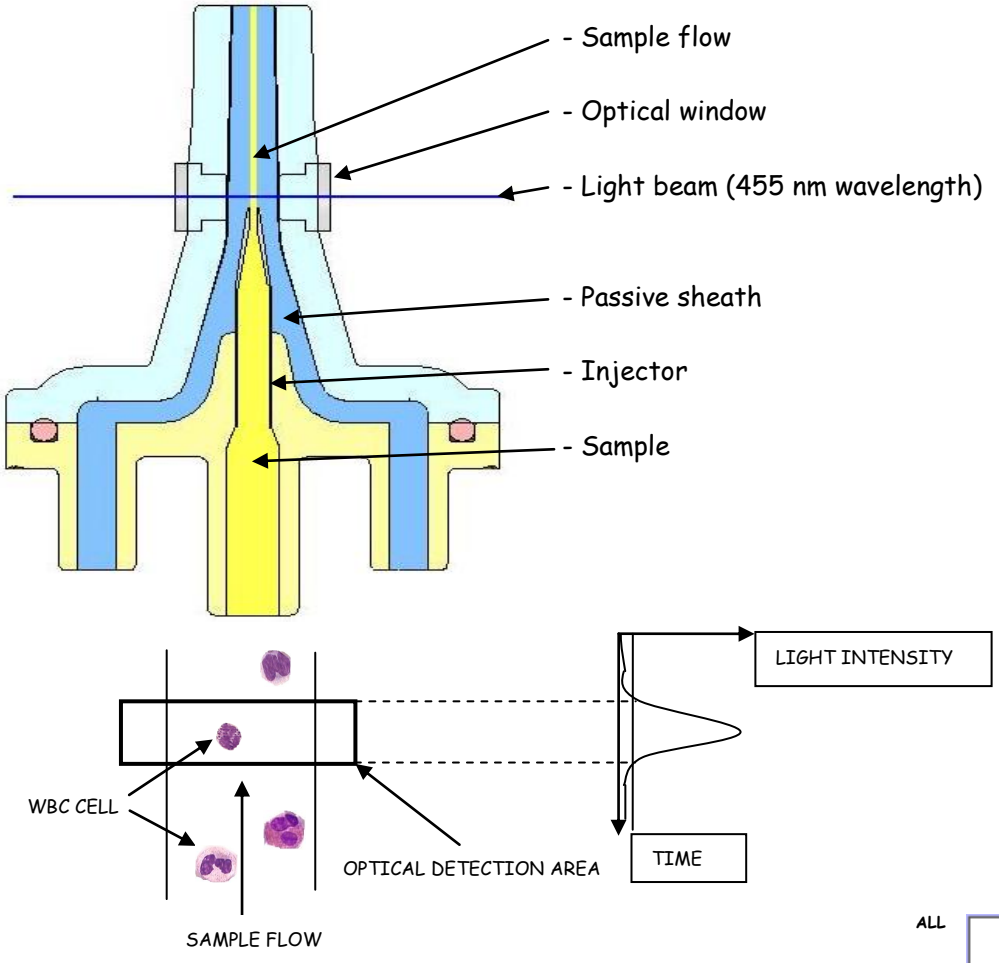
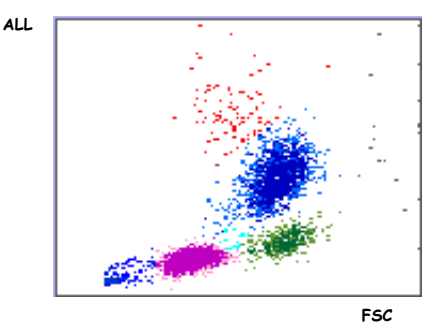
8.1.2 Five part diff measurement

The innovative optical detection system is covered by two patents pending. This technology (called **OCHF** for **O**ptical **C**ytometer **H**ydrofocus **F**ree) is based on an unique and innovative concept of an active sample flow and a passive sheath.
The sample flow is introduced in the flow cell under pressure and the sheath is only dedicated to maintain it. This principle enables to introduce a large quantity of sample and to use a great dilution rate (which allows to do the Hemoglobin measurement with the same dilution).
The main advantages are:

- High level of reliability of the optical adjustment.
- Only two measurement axes for five parameters.
- High resolution matrix.
- Only one passive sheath with low reagent consumption.
- No hydro focusing system.
- Low level of contamination between two measurements.
- Very low cost flow cell (injected plastic).



For each cell throwing the optical detection area, two pulses are generated, one for the Axis Loss Light (ALL) measurement and one for the Forward Side SCatter (FSC) measurement.
The result of those two axes of measurement is the high definition matrix that enables to identify five WBC populations.



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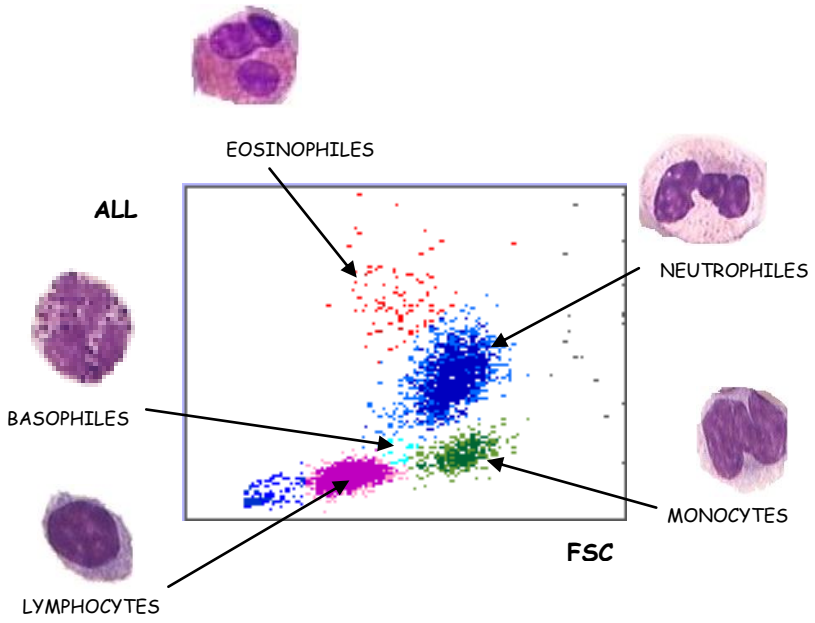
The five part diff is obtained by the optical matrix analysis after action of the lytic reagent (pending patent). This reagent destroys the RBC and their stromas, composes the oxy hemoglobin chromogen and protects the white blood cell membrane to keep it in closed native state.



8.1.3 Hemoglobin measurement

The hemoglobin measurement is directly done in the WBC chamber, by spectrophotometry at 555 nm. Hemoglobin is detected by formation of a chromogen oxy hemoglobin type (cyanide free technique).
A measurement of the blank of hemoglobin is done for each analytic cycle and during the start up rinsing step.
An automatic offset circuit for the LED 555 nm allows to maintain the blank level at the same range. It is not necessary to adjust this range with a potentiometer.

8.2 LEUCOCYTE ANALYSIS

The leukocyte number analysis is done by impedancemetry in the WBC counting chamber, the other ten parameters are obtained by flow cytometry measurement (see section **8.1.2**) :
All the thresholds of the differential are adjustable in the 20 blood types (see section **3.4.4.2**)

Parameters		Pathologies (adjustment section **3.4.4.1**)
WBC	White Blood Cells	Leucocytosis : WBC>WBC h Leucopenia : WBC<WBC b
LYM%	Lymphocytes in percentage	Lymphocytosis : LYM>LYM h (% &/or #) Lymphopenia : LYM<LYM b (%&/or #)
LYM#	Lymphocytes in value	
MON%	Monocytes in percentage	Monocytosis : MON>MON h (%&/or #)
MON#	Monocytes in value	
NEU%	Neutrophils in percentage	Neutrophilis : NEU > NEU h (%&/or #) Neutropenia : NEU < NEU b (%&/or #)
NEU#	Neutrophils in value	
EOS%	Eosinophils in percentage	Eosinophilis : EOS > EOS h (%&/or #)
EOS#	Eosinophils in value	
BAS%	Basophils in percentage	Basophilis : BAS > BAS h (%&/or #)
BAS#	Basophils in value	

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8.3 ERYTHROCYTE ANALYSIS

The erythrocyte analysis is done by impedancemetry in the RBC counting chamber and by analysis of the hemoglobin inside WBC chamber as previously described. Seven parameters are obtained:

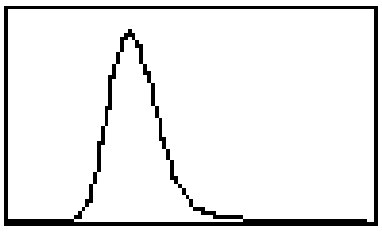
Parameters		Pathologies (adjustment section 3.4.4.1)
RBC	Red Blood Cells	Erythrocytosis : RBC>RBC h
HGB	Hemoglobin	Anemia : HGB < HGB b
HCT	Hematocrit	
MCV	Mean Corpuscular Volume	Microcytosis : VMC<VMC b Macrocytosis : VMC>VMC h
MCH	Mean Corpuscular Hemoglobin	
MCHC	Mean Corpuscular Hemoglobin Concentration	Hypochromia : MCHC<MCHC b Cold Agglutinin : MCHC>MCHC h
RDW	Red blood cells Distribution Width	Anisocytosis 1 : RDW>RDW h1

Hematocrit (**HCT**) is measured by integration volume of all of the red blood cells which flow in the RBC counting chamber aperture.
MCV is obtained by calculation, following the formula :

$$\textbf{MCV} = \frac{\text{HCT} \bullet 10}{\text{RBC}}$$

The RBC distribution curve analysis allows the measurement of **RDW**. RDW is an expression of the standard deviation divided by MCV. This parameter evaluates the RBC anisocytosis.

$$\textbf{RDW} = \frac{k \bullet SD}{MCV}$$



Wintrobe constant calculation :
The Mean Corpuscular Hemoglobin (MCH) calculation is made from HGB and RBC by the formula below :

$$\textbf{MCH} = \frac{\text{HGB} \bullet 10}{\text{RBC}}$$

The Mean Corpuscular Hemoglobin Concentration (MCHC) is made from HGB and HCT by the formula below :

$$\textbf{MCHC} = \frac{\text{HGB} \bullet 100}{\text{HCT}}$$

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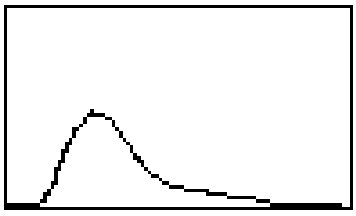
8.4 ANALYSIS OF PLATELETS

Platelet analysis is made by impedancemetry in the RBC counting chamber at the same time with red blood cells. Four parameters are obtained:

Parameters		Pathologies (adjustment section 3.4.4.1)
PLT	Platelets	Thrombopenia : PLT<PLT b Thrombocytosis : PLT>PLT h
MPV	Mean Platelet Volume	Giant platelets : MPV> MPV h
PDW	Platelet Distribution Width	
PCT	Thrombocrit	

The analysis of the platelet distribution curve allows to measure the Mean Platelet Volume (**MPV**) and the Platelet Distribution Width (**PDW**).
Thrombocrit (**PCT**) is made from PLT and MPV by formula below :



$$\mathbf{PCT} = \frac{PLT \bullet MPV}{10000}$$

8.5 FLAGS

MYTHIC 22 CT manages 25 different flags. These flags allow the user to be alerted if there is a problem which can affect the quality of the results. All of these flags appear on the right of the result.

In presence of one or more flags, it is recommended to check the result by a conventional measure or on blood smear.

NOTA : Most of these flags can be modified by the user (see section 3).

8.5.1 General Flags

The following alarms are common for all parameters.
XXX *****: Counting or measure rejection . Can appear with WBC, RBC, PLT and HGB (see section 8.5.3 for HGB and section 8.5.2 for DIF parameters).
XXX**D**: Higher than linearity limits but lower than the reportable limits. WBC, RBC, PLT, HCT, HGB.
+++D: Higher than the reportable limits. WBC, RBC, PLT, HCT, HGB.
----: Rejected value.
h: results higher than normal value.
b: results lower than normal value.
H: results higher than panic value.
B: results lower than panic value.

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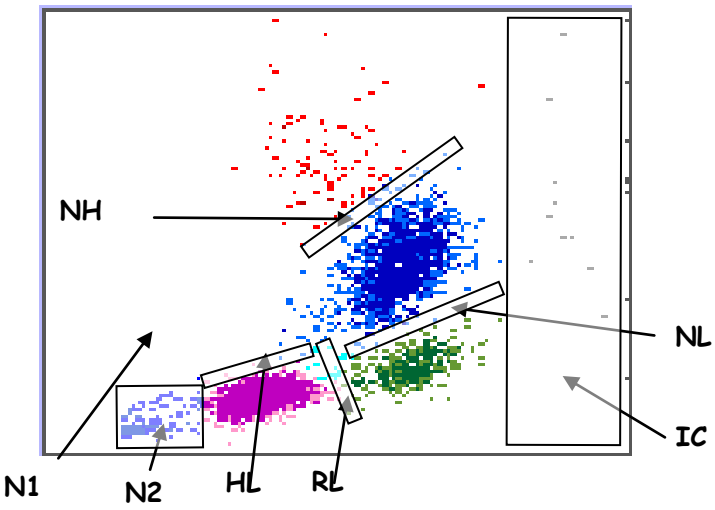
8.5.2 Instrument Flags

W_CL : Suspicion of WBC aperture clog, if it persists run a concentrated cleaning (see section 9.1.2).
R_CL : Suspicion of RBC aperture clog, if it persists run a concentrated cleaning (see section 9.1.2).
O_CL : Suspicion of Optical injector clog, if it persists run a concentrated cleaning (see section 9.1.2).
OPT- : Counting gap between resistive and optical WBC count, if it persists run a concentrated cleaning (see section 9.1.2)
INS_H : HGB channel saturation, run a START UP cycle.
INS_T : A temperature (enclosure, reagents or ambient) is out of range (see section 9.5.2)
INS_P : Pressure default (see section 9.5.2).

8.5.3 Leucocytes Flags

SCATTERGRAM FLAGS:



All the followings flags levels are adjustable in the 20 types of blood (see section 3.4.4).
Number of cells in a zone:

N1 (**N**oise **1**): Presence of platelet aggregate, debris or resistant RBC
N2 (**N**oise **2**): Presence of platelet aggregate, erythroblast or small lymphocytes.
IC: Presence of **I**mmature **C**ells (from the mono or polynucleated cells line)

Number of cells located of each side of the threshold :

RL (**R**ight **L**ymphocytes : Presence of atypical lymphocytes or basophiles.
HL (**H**igh **L**ymphocytes): Presence of basophiles, small Neutrophils (without granulations or few segmented), band cells.
NL (**N**eutrophils **L**ow): Presence of small Neutrophils (without granulations or few segmented), band cells or hyper basophil Monocytes.
NH (**N**eutrophils **H**igh): Presence of giant Neutrophils, hyper segmented Neutrophils, eosinophils with few granulations or damaged eosinophils.

- The WBC flags appear when the % limit **AND** # limit are reached.

	These flags may appear if the blood was not store in good conditions or if it was sampled too much (more than 30 times).

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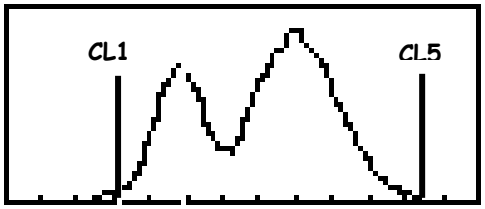
DIF parameters display rules :

- If one or more DIF parameters (LYC, MON, NEU, EOS or BAS) are following with a star (XXX *) the sample must be checked on smear.
- Basophile result must be checked on smear if it is following by a star (XXX *).

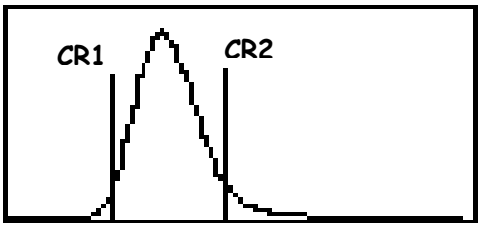
WBC CURVE FLAGS :

This curve is done by the WBC channel measurement and does not appear on the normal results screen. The flags L1 and L5 complete the flags N2 and IC.



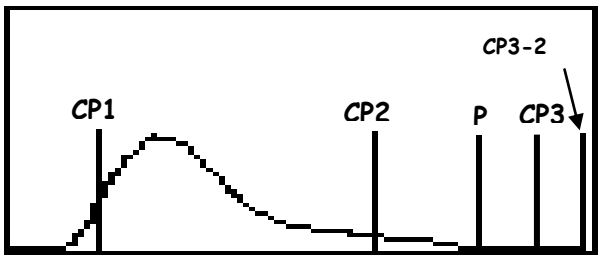
L1 = Presence of platelet aggregate, erythroblast or small lymphocytes at the left of **CL1**.
L5 = Presence of immature cells at the right of **CL5**.

8.5.4 Erythrocyte and HGB Flags



R1 = Abnormal quantity of microcytes at the left side of **CR1**.
R2 = Abnormal quantity of macrocytes at the right side of **CR2**.
HGB : * means bad measure of the HGB blank.

8.5.4 Platelet Flags



P1 = **0** to **CP1** : Presence of abnormal quantity of debris or small cells.
P2 = **P** to **CP2** : Presence of schizocytes.
P3 = **CP3** to **CP3-2**: Presence of microcytes.

- The RBC and PLT flags appear when the % limit **OR** # limit are reached

8.5.5 QC Flags

QC_F : QC Failed. This flags appear when the result of the QC run was out of the limits. This flag is printed with each result.
QC_ND : QC Not Done, this flags appear when no QC was run before the analysis of samples. This flag is printed with each result. See section **6**.

8.5.6 STARTUP Flags

SU_F : STARTUP Failed. This flag appear when samples are run after a bad START UP. This flag is printed with each result.
SU_ND : STARTUP not done. This flag appear when samples are run without START UP running. This flag is printed with each result. See section **5.4**.

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8.6 HYDRAULIC DESCRIPTION

The hydraulic part of the **MYTHIC 22 CT** is very simple and made of these modules :

- Sampling module.
- Counting bath module.
- Syringes module.
- Optical manifold.
- Optical bench.

The modules are connected together by semi rigid tubing.

8.6.1 Sampling module

This module (two patents pending) enables to pierce the cap of the sample tube with only one needle, to draw the sample and to perform the WBC and RBC/PLT dilutions.
It is assembled with a rotating rocker moving around a support which maintains the system to move up and down the sampling needle. A very reliable system of rack-gear moves the rocker.
The cleaning system of the sampling needle can be removed without tool (see section **9.3.2**).
The o-ring of the needle included in the cleaning system can also be removed without tool (see section **9.3.2**). The maintenance of these parts is very easy to perform.
The sample tube is maintained by a system of tube holder dedicated to each type of tube.
The tube holder is maintained by a door driven to close or open by a motor.

8.6.2 Counting bath module

This module allows to count the WBC and RBC/PLA and to measure the HGB.
It is made with a manifold maintaining the reagent commutation valves and the counting bath block with their measurement block including the apertures.
The counting bath block assembly and these apertures can be removed without tool (see section **9.3.3**/**4**/**5**).

8.6.3 Syringes module

This module (two patents pending) enables:

- to draw the sample
- to distribute the reagents
- to drain the baths
- to do the vacuum necessary for counting
- to push the waste to the waste container
- to push the WBC sample and the diluent sheath in the flow cell .

It is made with a manifold maintaining the fluid commutation valves and with the syringes bloc including five syringes :

- The sampling syringe
- The lysis syringe
- The two waste and vacuum/pressure syringes
- And the diluent syringe.

Only one motor drives the five syringes.
The diluent input and the waste output are also included in this manifold.

8.6.4 Optical manifold

This manifold allows to drive the different reagent toward the counting bath module or toward the optical bench. It maintain seven commutation valves

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8.6.5 Optical bench

This very important part (two pending patents) allows to measure the leucocytes sub population.
It is made of three parts :
- an illumination module : which contain the semi conductor light source, a beam adjustment glass smear, and lens.
- a flow cell : made in injected plastic in which the sample and the passive sheath flow away.
- and the detection module : which contains lens, a beam separation glass smear, photodiodes and the amplifier boards for the two measurement axes.

8.8 SOFTWARE

8.8.1 Windows

Common keys:

This three keys

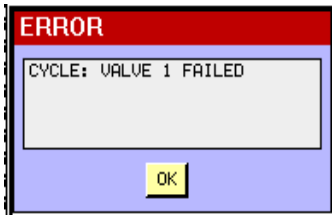
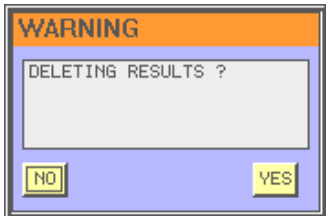
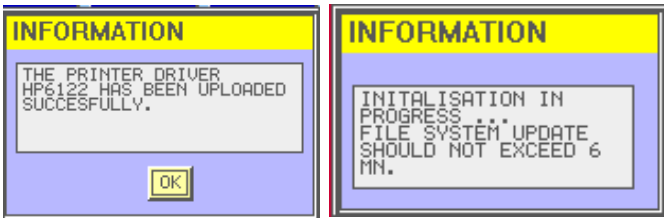
are always present in all screen

allows to come back to the previous display.

allows to come back to the MENU display where ever you are in the arborescence.

depends on the screen it allows to open a window dedicated to perform an action, for example to select information, to print, send, save or delete it.

Windows :

		
Means an **ERROR** occurred, it is mandatory to do the action describe in the window or in the table section 9.6.	**WARNING** : You have to confirm or not the action describe in the window.	**INFORMATION** window.

8.8.2 Menu tree

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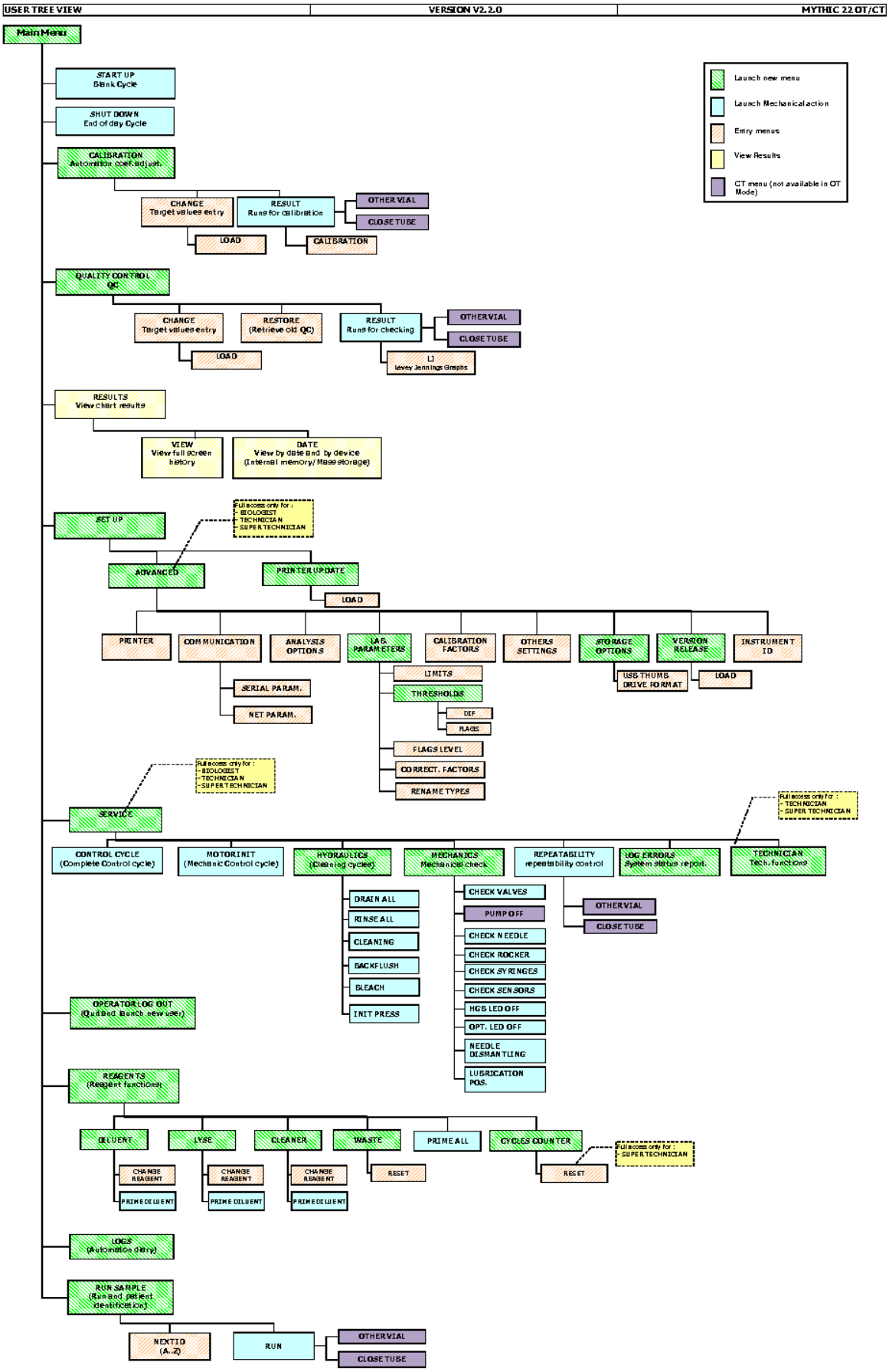

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9. SERVICE

The quality of the results and the reliability of the **MYTHIC 22 CT** are directly linked to the strict respect of the maintenance hereafter described.

To perform the maintenance and the repair described in this section, it is mandatory to have received adequate training, to wear rubber gloves and wash hands with a disinfectant after completion of work.

9.1 MAINTENANCE

9.1.1 Maintenance table

NOTA: This table is made for an average number of 50 samples per day. For more, please increase proportionally the number of maintenances.

MAINTENANCE	DAILY		WEEKLY		QUARTERNALY (or ~3750 cycles)		HALF A YEAR (or ~7500 cycles)		ANNUALLY (or ~15000cycles)	
	User	Tech	User	Tech	User	Tech	User	Tech	User	Tech
Reagents level	X									
Start Up	X									
Automatic cleaning	X									
Concentrate cleaning			X							X
Shut down	X									
Cover cleaning	X									X
Piston greasing					X					X
In line filter cleaning					X					X
Needle o-ring replacement							X			X
Syringes o-ring replacement										X
Motor screw greasing										X
Pump Drying										X

MAINTENANCE TO BE DONE BY THE USER (yellow boxes):

- Reagents level control: see section **5.3**
- Start up: see section **5.2**
- Automatic Cleaning: The cleaning is automatically performed by the **MYTHIC 22 CT** following the set up defined by the user (see section **3.3.6**). (the standard value is 80).

Increase the frequency of the cleaning of the **MYTHIC 22 CT** in case of analyzes of pathological samples or if there are too many flags and too often.

- Concentrated cleaning: see the following section **9.1.2**
- Shut down: see section **5.11**
- Cover cleaning: Clean the cover above and around the sampling needle with a wet paper with a disinfectant to eliminate the blood trace.
- Piston greasing: see section **9.1.3**
- In line filter cleaning: see section **9.1.4**
- Needle o-ring replacement: see section **9.4.2**
- Pump drying: The pump is checked and cleaned every year.

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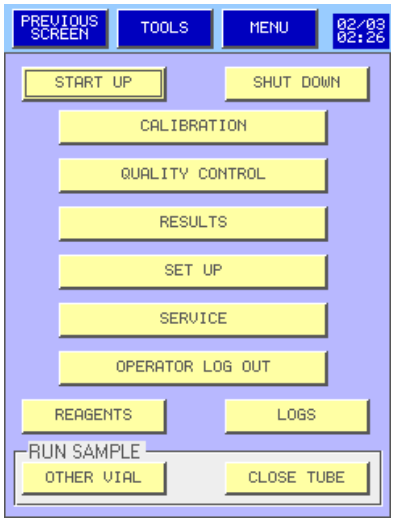
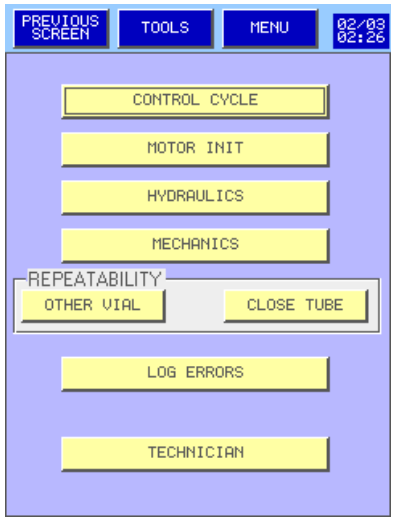
9.1.2 Concentrate cleaning

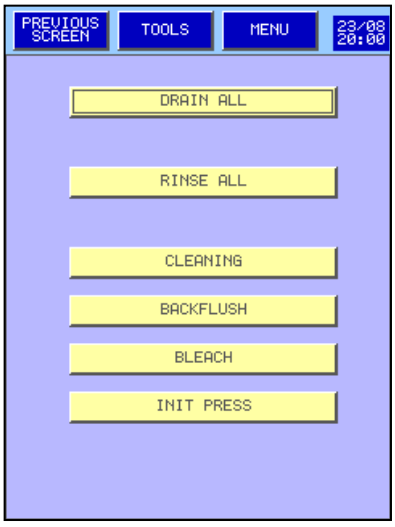
This cleaning is necessary once a week to clean the WBC bath or when **MYTHIC 22 CT** is in permanent rejection for one measured parameter or permanent clog flag (see section 8.1.5).
Prepare a Sodium Hypochlorite solution at 12° in chloride (diluted 4 times with distilled water if sodium hypochlorite is concentrated at 48° in chloride or three time with 36°).



- Return to the main menu by pressing MENU.
- Then press SERVICE.



- Press HYDRAULICS.



- Press BLEACH to start the cycle (drain the counting chamber).

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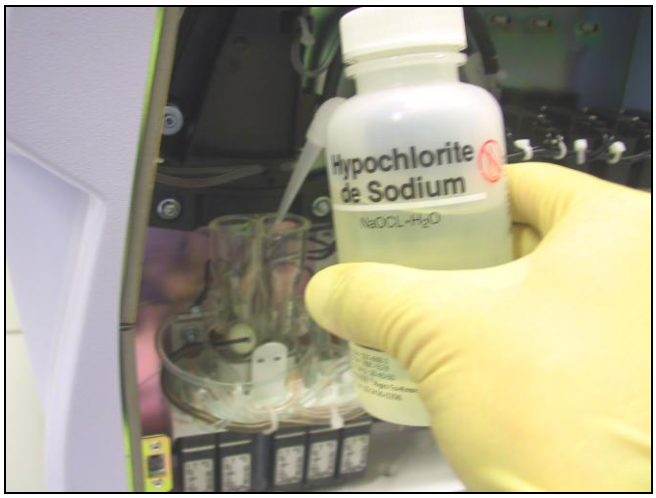
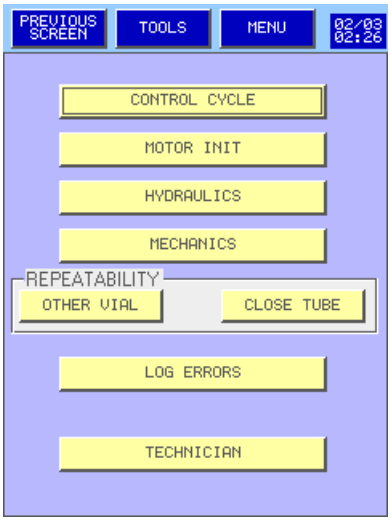


- Open the door on the right side (see section 1.1.3).
- Put **3** ml of sodium hypochlorite solution in each counting chamber.
- Press the button in the window located in the screen center.
- **MYTHIC 22 CT** performs a maintenance cycle of the apertures and the flow cell follow with a stand by mode during 2 min.
- After 2 min. **MYTHIC 22 CT** rinses all of the elements. Operator can perform an analytic cycle.

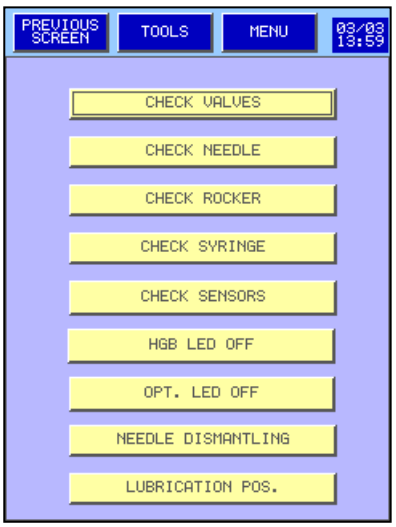
	Wear rubber gloves and wash hands with a disinfectant after completion of work.

9.1.3 Piston greasing



- To have access to the hydraulic cycle, press SERVICE from the **MAIN MENU**, then press MECHANICS

	Operators must be trained and to know that due to moving parts there is a risk to pinch their fingers between pistons and the syringe body.



- Press LUBRICATION POS. to put the piston of the syringe module in the greasing position.

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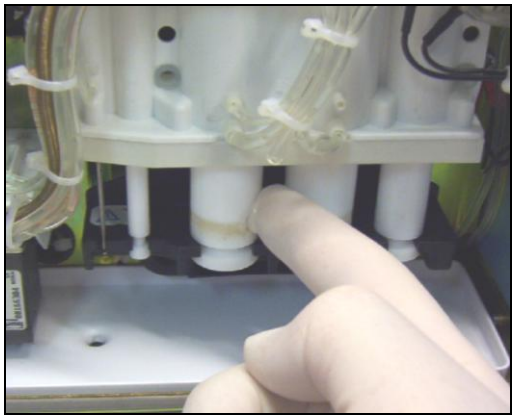
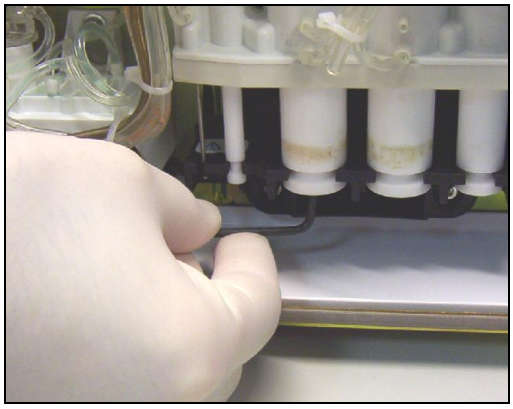
Wear rubber gloves and wash hands with a disinfectant after completion of work.

- Open the door on the right side (see section 1.1.3).
- Put a small nut of grease on a finger.

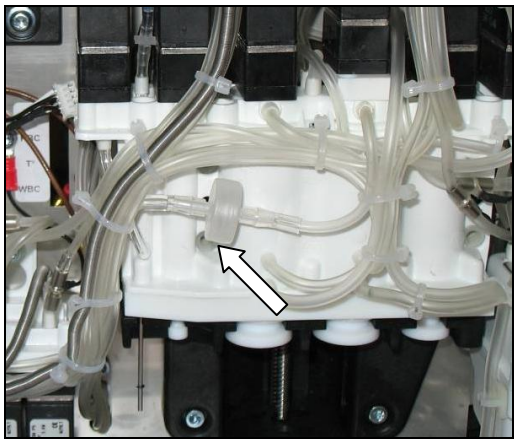


- Put a **THIN FILM** of grease around each piston.



- Turn the two big pistons (waste pistons) with the help of the key supplied in the installation kit.
- Continue to put a thin film of grease around each piston.
- The other pistons can be turned with fingers.

9.1.4 In line filter cleaning



- The in line filter allows to eliminate the small piece of rubber cap which could be created in case of multiple sampling of the same sample or if the rubber cap quality is poor.

Wear rubber gloves and wash hands with a disinfectant after completion of work.

Clean or exchange the filter following the maintenance table (see section 9.1.1) or when the message "Pressure default" appear (see section 9.5.2).

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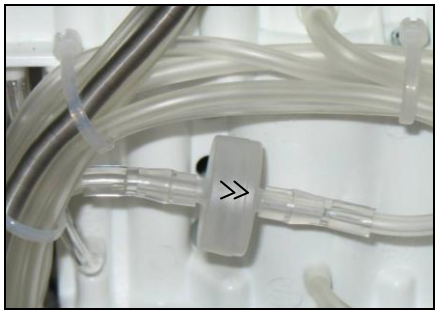
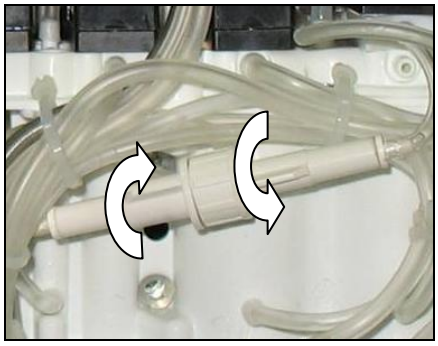


- This type of filter is disposable and must be throw away when it is blocked.
- Be aware to not reuse inline filter upside down. It could inject small parts in to valves and generate malfunction.

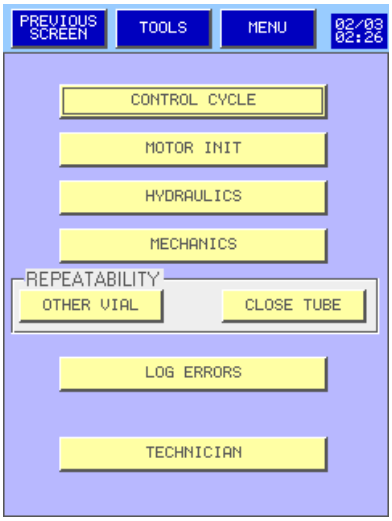


- Open this type of filter older then clean the filter cartridge with a disinfectant and remove the pieces of rubber.

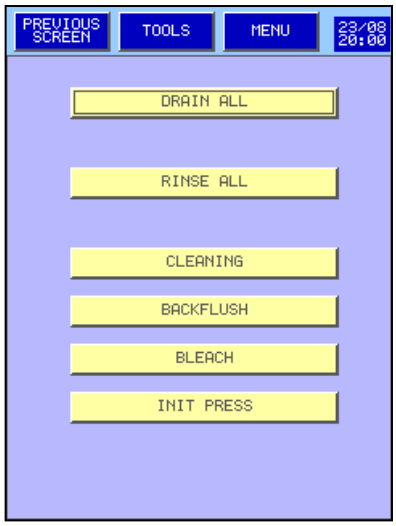
- Reassemble the filter cartridge and the filter holder.

- Take attention to well closed the filter holder.

9.2 HYDRAULIC CYCLES



- To have access to the hydraulic cycle, press SERVICE from the **MAIN MENU**, then press HYDRAULICS



- To drain the counting baths the flow cell and the waste syringes, press DRAIN ALL

- To fill the counting baths and the flow cell with diluent, press RINSE ALL

- To perform a cleaning of the aperture blocks and the flow cell with the cleaner, press CLEANING

- To perform a back flush in the aperture blocks and the flow cell, press BACKFLUSH

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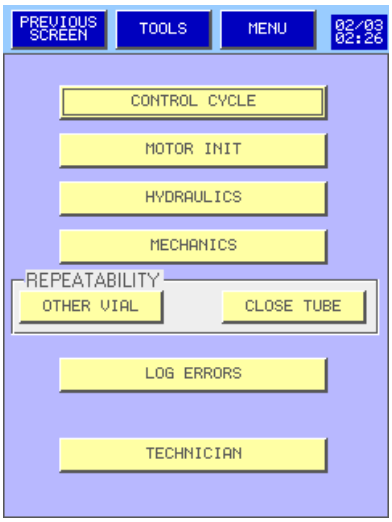
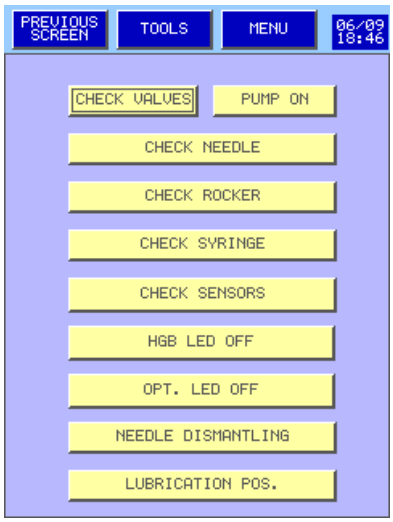
9.3 MECHANICS



- To have access to this cycle, press SERVICE from the **MAIN MENU**, then press MECHANICS



CHECK VALVES and CHECK SENSORS see below.

CHECK NEEDLE performs a complete test of the needle.

CHECK ROCKER performs a complete test of the rocker.

CHECK SYRINGE performs a complete test of the syringe.

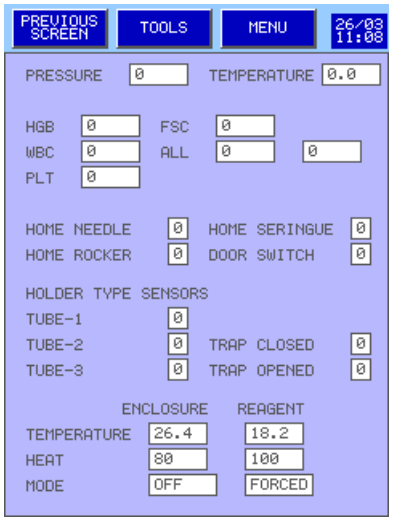
PUMP ON switches on (or off) the pump to check it

HGB LED OFF switches on (or off) the HGB led to check it.

OPT. LED OFF switches on (or off) the optical led to check it.

NEEDLE DISMANTLING see section 9.4.2

LUBRICATION POS. see section 9.1.3



- This screen allows to check if the different sensors are available in case of problem.

> **NOTA** : To understand the function of each sensor we recommend to do an Orphée's training.

- Range of trigger temperature measured by the sensors:
  - Ambient: 17°C <--> 35°C
  - Enclosure: 32°C <--> 40°C
  - Reagents: 34°C <--> 45°C

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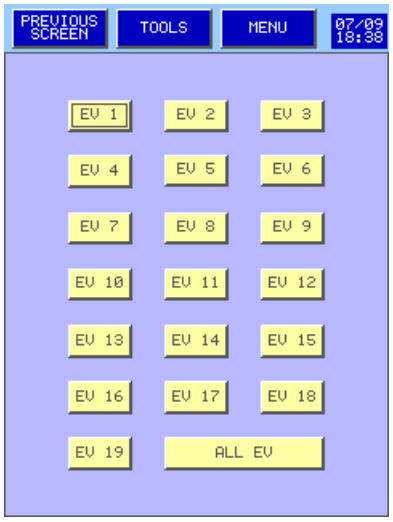
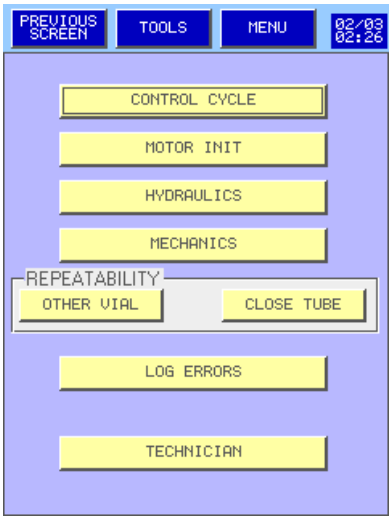


- To test each valve, press the dedicated button.

- To test all the valves press ALL EV

9.4 REPAIRING

9.4.1 Emergency stop



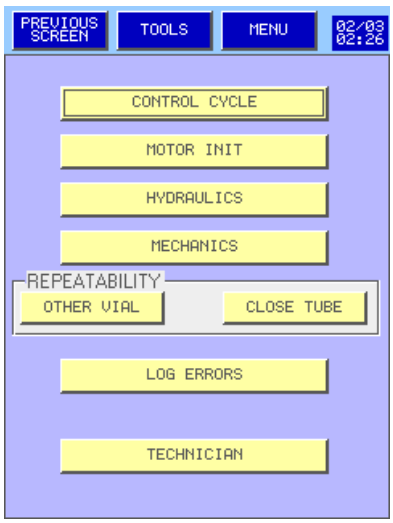
In case of mechanical or hydraulic problem, immediately press , the **MYTHIC 22 CT** will make an emergency stop.

- After having identified the problem, it is necessary to perform a Control cycle.

- To have access to this cycle, press SERVICE from the **MAIN MENU**, then press CONTROL CYCLE

9.4.2 Needle or o-ring replacement

	Wear rubber gloves and wash hands with a disinfectant after completion of work. **The replacement of the o-ring is MANDATORY for each disassembling of the needle.**



- From the main menu, press SERVICE then MECHANICS to go to the display described on the left.
- Press on NEEDLE DISMANTLING
- The rocker places the sampling needle in the disassembling position.
- Open the door located on the right side to have access to the hydraulic part.

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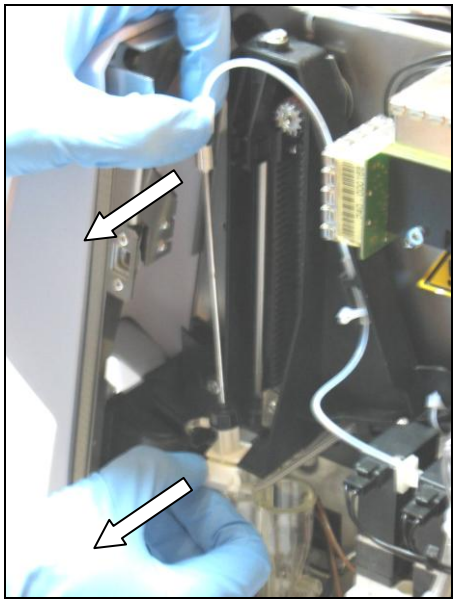
- The needle is in front of the counting chambers

- First remove the top of the needle from the clip, lets the needle free in front of the clip (do not pull a lot the upper needle).

- Remove the sampling module, while slightly lowering the clip to the bottom.



- Pull the needle and the rinsing head system towards outside.

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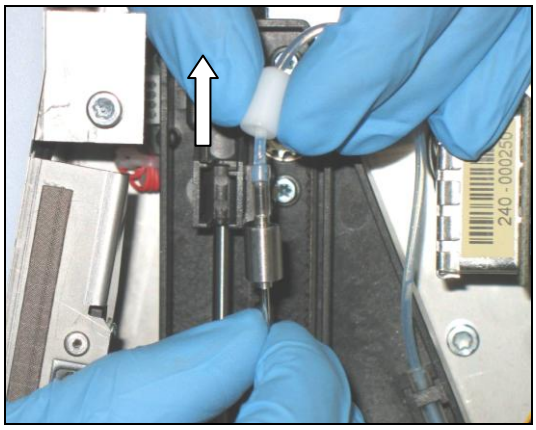
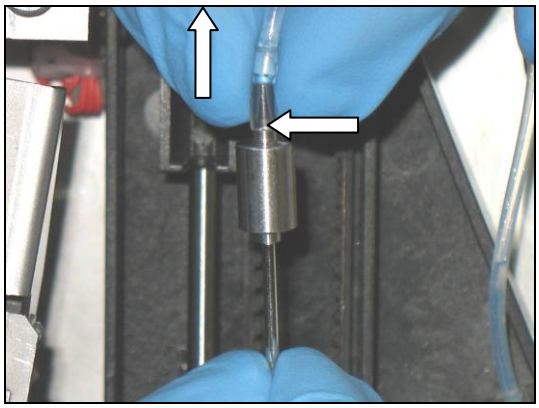
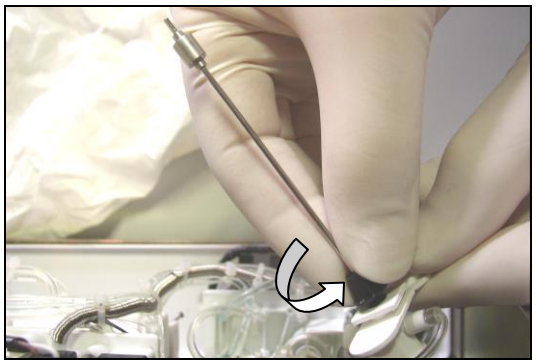


- Lift the sleeve only if you want exchange the needle.

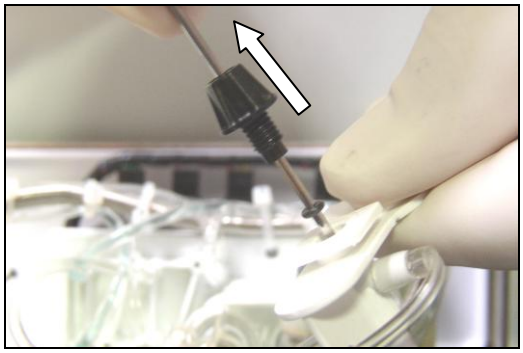
- Lets the tubing connected and the sleeve in place if you exchange only the o-ring.



- Remove the tubing fixed at the end of the needle only if you want exchange the needle.
- Do not pull the Teflon tubing but the crystal tubing.
- Lets the tubing connected if you exchange only the o-ring.



- Unscrew the serrated roller which maintains the seal and the needle.



- Leave the serrated roller, the needle and the o-ring from the rinsing head.

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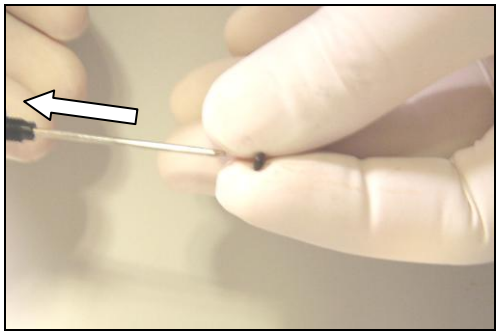


- Remove the o-ring.
- Replace the needle and/or the o-ring.

	Grease only the o-ring. If the needle is greased, the grease could block the grooves and create diluent leak and the results will be altered.

REASSEMBLY PROCEDURE :

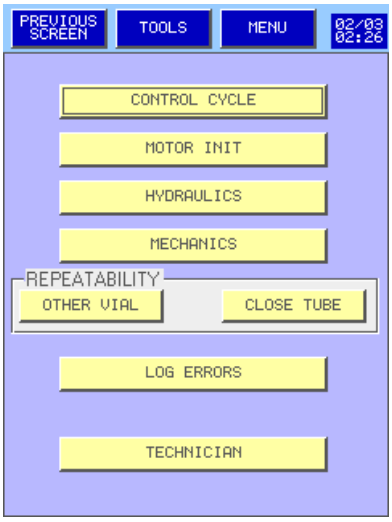
To reassemble the unit, carry out the various operations in the opposite direction. Place the seal on the needle gently not to wound it.

	Do not grease the needle after removing. If the needle is greased, the grease could block the grooves and create diluent leak and the results will be altered.

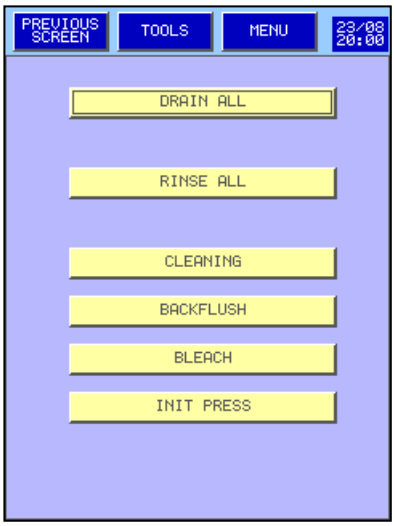
9.4.3 Baths dismantling

This procedure must be carried out to replace the bath seals on the manifold or the aperture seals.

	Wear rubber gloves and wash hands with a disinfectant after completion of work.



- From the **MAIN MENU**, press SERVICE then press HYDRAULICS.



- Press DRAIN ALL to perform a draining of the counting baths.

- Open the door located on the right side of the instrument to have access to the hydraulic part.

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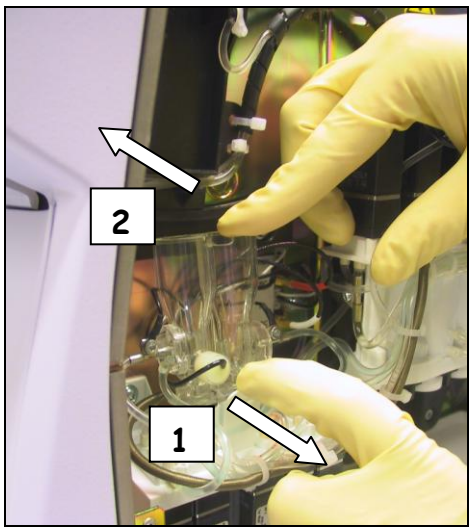
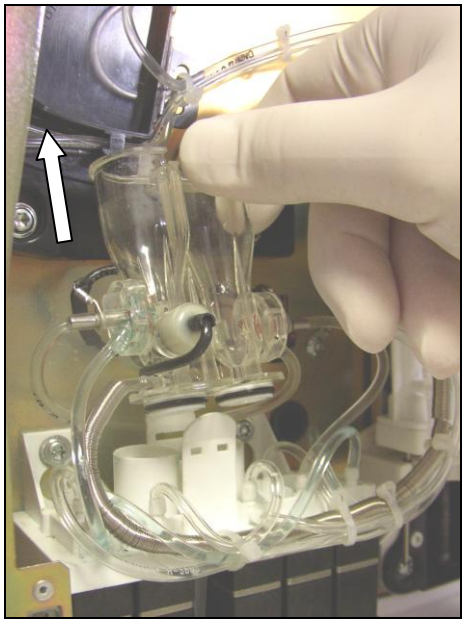
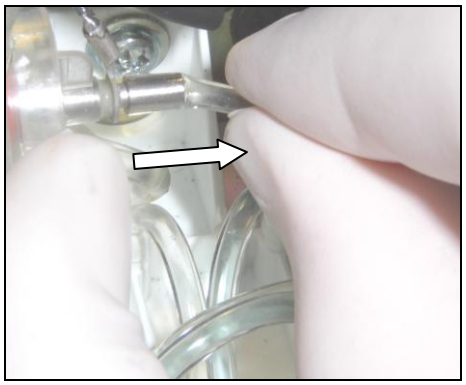


- To remove the counting bath module, pull on the clip **1** while pushing the top from the counting bath towards the inside of the machine **2** .



- Then, upwards, raise the counting module.



- Next, remove the tubing fixed on the RBC counting head, located on the right side of the counting module.

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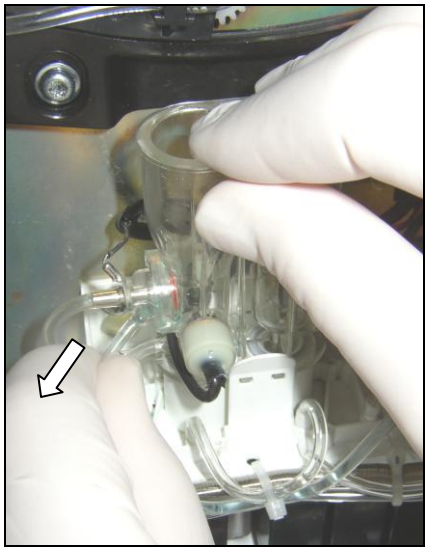
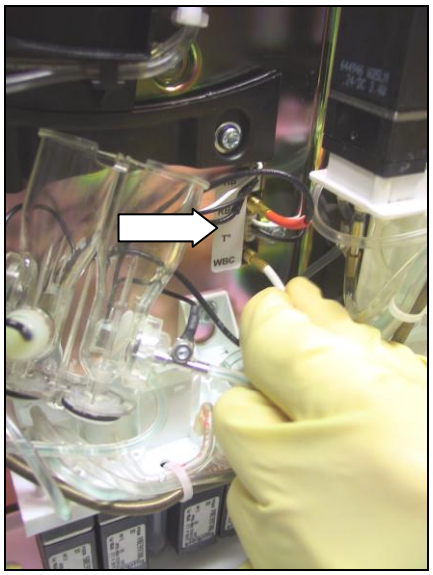


- Remove the tubing fixed on the plastic fitting located under the stainless tube from WBC counting block.



- Remove all connectors.

- The counting bath module can now be handled to carry out the desired operations of replacement.

REASSEMBLY PROCEDURE :

To reassemble the unit, carry out the various operations in the opposite direction.

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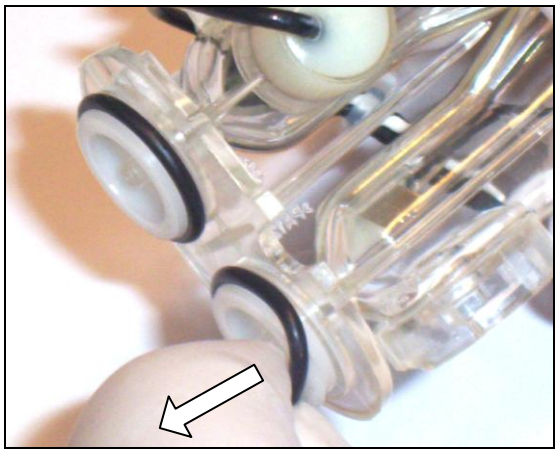
9.4.4 Baths o-ring replacement

	Wear rubber gloves and wash hands with a disinfectant after completion of work.



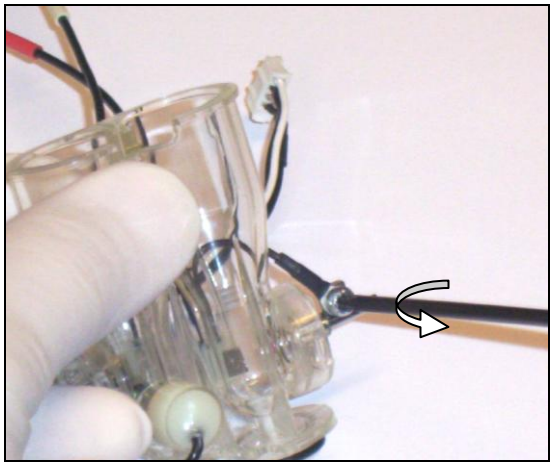
- Before performing the operation, drain the baths and dismantle the counting bath block (see section **9.4.3**).

- Replace the o-ring and/or the complete bath block.

REASSEMBLY PROCEDURE :
To reassemble the unit, carry out the various operations in the opposite direction.
Place the seal on the counting bath gently not to wound it.

9.4.5 Aperture block replacement

	Wear rubber gloves and wash hands with a disinfectant after completion of work.

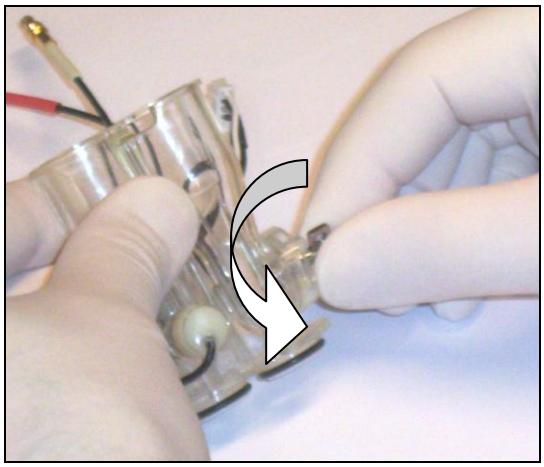


- Before performing the operation, drain the baths and dismantle the counting bath block (see section **9.4.3**).

- Remove the tubing from the blocks to be replaced.

- With the help of the provided tool in the maintenance kit, unscrew the screw and remove the connection.

NOTA : This operation can be performed without dismantling the complete bath block.



- Unscrew the aperture block of a quarter of turn.

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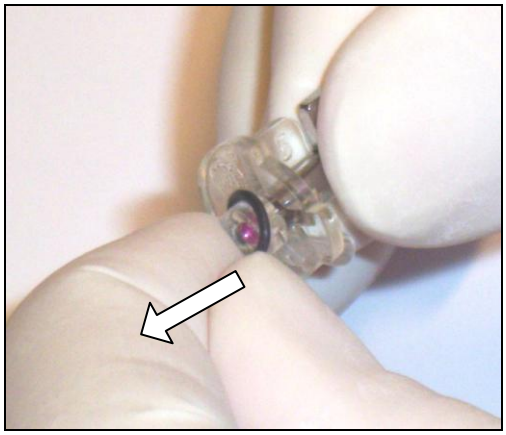

- Remove the o-ring and replace by a new one or replace the whole part.

NOTA : The WBC aperture block is marked with a figure **8** on the ear and with a figure **5** for the RBC.

REASSEMBLY PROCEDURE :

To reassemble the unit, carry out the various operations in the opposite direction.
Place the seal on the aperture block gently not to wound it.

9.5 TROUBLESHOOTING

In any case, if a problem is not solved, call Orphée's representative.

9.5.1 Analytical problems

PARAMETERS	PROBLEMS	CONDITIONS	SOLUTIONS
WBC	No result	No HGB	Check the lysis level. Check the right lysis tubing connection to the WBC bath. Check the valve Nb 9.
		HGB OK	Check the bath wires. Perform a Cleaning Cycle and then a Bleach cycle if unsuccessful. Change the aperture block if unsuccessful.
	Bad stability		Perform a Back flush and a Cleaning Cycle and then a Bleach cycle if unsuccessful. Check the level bubble flow in the WBC bath during the run cycle. Check the reagent and enclosure temperature.
5 DIFF	No result or bad stability	No HGB & WBC	Check the lysis level. Check the right lysis tubing connection to the WBC bath. Check the valve Nb 9.
		HGB & WBC OK	Perform a Back flush Cycle and then a Bleach cycle if unsuccessful. Check the valves Nb 12, 13, 16 & 17. Check the reagent and enclosure temperature. Check the preampli connection wires.
	Rejection	*	Check the results on blood smear.
RBC	No result	No HCT & PLT	Check the bath wires. Perform a Cleaning Cycle and then a Bleach cycle if unsuccessful.
	Bad stability	HCT & PLT	Perform a Back flush and a Cleaning Cycle and then a Bleach cycle if unsuccessful. Check the level bubble flow in the RBC bath during the run cycle. Check the level bubble flow in the WBC bath during the first dilution.

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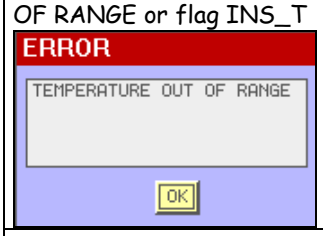
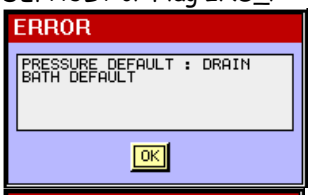
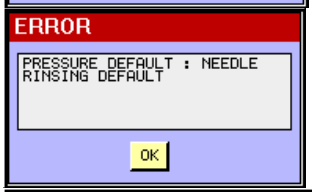
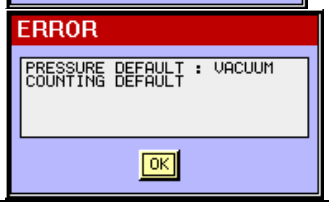
PARAMETERS	PROBLEMS	CONDITIONS	SOLUTIONS
HGB	No result		Check the led light on
	Bad stability		Check if no bubble in the lysis tubing. Check the reagent and enclosure temperature. Check the level bubble flow in the WBC bath during the run cycle.
	Rejection	--- *	Close the door. Perform a new Start Up cycle.
	Flag INS_H		Close the door. Perform a new Start Up cycle.

9.5.2 Other problems

ORIGIN	PROBLEMS	SOLUTIONS
MYTHIC	Diluent leaks around the needle during the run cycle	Check the rinsing needle block (presence of clots) and clean it if necessary. Clean the needle for removing the grease in the grooves, see section 9.4.2
	No starting	Check the power supply connection wires Check the switch on button located on the power supply block.
	All results bad	Check the level diluent and if the tubing is pinched. Check if the diluent is at the same level than the analyzer.
	No display	Check the flat cable.
	ID and/or PID typing impossible	ID and/or PID are mandatory (see section 3.4.3).
	Message : TEMPERATURE OUT OF RANGE or flag INS_T 	Check the origin of the problem of temperature in section 9.3. Trigger temperature values: Ambient: 17°C <--> 37°C Enclosure: 33°C <--> 40°C Reagents: 34°C <--> 45°C
	Message: CYCLE: PRESSURE DEFAULT or Flag INS_P   	Cases of occurrence: - drain chamber default: check the tubing connection of the fluidics - rinsing head default: check the in line filter locking (see section 9.1.4) and the pump operation - counting vacuum default: perform a piston greasing (see section 9.1.3) and check the tubing connection of the fluidics For all occurrences check also the level of the reagents.
Printer	No printing	Check the paper. Check the electrical connection.
	Bad printing	Check the ink ribbon or the ink cartridge.

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9.6 TROUBLESHOOTING MESSAGE

This section allows to know what to do when a troubleshooting message appears on the screen.
If the problem go on contact your Orphée's representative.

MESSAGE	ACTION
BACKUP : FOLDER NOT FOUND	Re-start the Mythic.
BACKUP: BAD FOLDER DUPLICATION	Re-start the Mythic.
BACKUP: CALIBRATION HISTORY IS FULL	Delete the calibration results.
BACKUP: FAIL TO SAVE RESULT ONTO THE EXTERNAL STORAGE DEVICE. THE INTERNAL MEMORY IS USED.	Check if the USB thumb drive is connected to the analyzer.
BACKUP: FILE SYSTEM FAILED.	Re-start the Mythic.
BACKUP: LAST QC RESTORED.	File has been restored to previous state
BACKUP: LAST RESULT SAVED.	Memory full, next result will not be saved. You have to delete results.
BACKUP: LAST RESULTS RESTORED.	File has been restored to previous state
BACKUP: LAST SETUP RESTORED.	Indicate that your SETUP has been restored
BACKUP: MEMORY IS ALMOST FULL. PLEASE DELETE RESULTS.	Delete results
BACKUP: NO MEMORY AVAILABLE FOR STORAGE	Delete the stored results.
BACKUP: PARTIAL CALI. RES. DELETED.	A bad Result storage happened
BACKUP: PARTIAL NUM DELETED.	A bad Result storage happened
BACKUP: PARTIAL QC RES. DELETED.	A bad Result storage happened
BACKUP: PARTIAL REPET. RES. DELETED.	A bad Result storage happened
BACKUP: QC HISTORY IS FULL	Delete the Q.C. results of the ongoing lot.
BACKUP: REPAIR SECTOR DONE.	Internal database as been restored after detecting incoherent
BACKUP: REPEATABILITY HISTORY IS FULL	Delete the repeatability results.
BACKUP: SECTOR FAILED.	Hardware failure on memory
BACKUP: SETUP UPDATED WITH DEFAULT VALUES.	Indicate that your SETUP has been released
BACKUP: SYSTEM ERROR	Re-start the Mythic.
CLEAN NOT DONE	Perform a rinse cycle.
CLEANER ALMOST EMPTY	Replace the bottle and perform a prime Cleaner
COM: BAD CYCLE MODULE	Rebuild cycles with good options
COM: CRC CONTROL ERROR	Communication error retry
COM: SIZE ERROR.	Try again, if the problem occur, call an Orphée representative.
CONTROL CYCLE NOT DONE	Perform a control cycle.
CYCLE : PUMP COMMAND FAILED.	Check the pump connection.
CYCLE STOPPED BY USER	Emergency stop, please perform a control cycle.
CYCLE: BUSY	Wait before performing a cycle.
CYCLE: CMD VALVE FAILED	Change the valve
CYCLE: EMERGENCY STOP	Perform a control cycle.
CYCLE: FLUIDIC DOOR OPENED	Close the Fluidic door. Run Control cycle.
CYCLE: HGB CHANNEL SATURATION. PLEASE RUN STARTUP.	Run Startup Cycle. If the problem still occurs, Call an Orphée representative.
CYCLE: INIT NOT DONE	Perform an initialization or a control cycle.
CYCLE: PRESSURE DEFAULT	May occurred by leak of reagent or check tubing in the fluidics.
CYCLE: VALVE 1 FAILED	Change the valve
DILUENT ALMOST EMPTY	Replace the container and perform a prime Diluent
HARDWARE: A.L.L BOARD ID FAILED.	Check the hardware connection on ALL Board
HARDWARE: F.S.C BOARD ID FAILED.	Check the hardware connection on FSC Board
HARDWARE: FAN FAILED.	Check if your temperature fan is running
HARDWARE: HEAT ENCLOSURE FAILED.	Call an Orphée representative.
HARDWARE: HEAT ENCLOSURE STOPPED.	Check your enclosure sensor
HARDWARE: HEAT REAGENT FAILED.	Call an Orphée representative.
HARDWARE: HEAT REAGENT STOPPED.	Check your reagent sensor
HARDWARE: SYSTEM ERROR	Re-start the Mythic.
HEATING IN PROGRESS, PLEASE WAIT.	Wait for the system to reach its temperature
HOLDER: TOO MUCH STEP DONE. ADJUST CYCLE FAILED.	Message reserved to the service people.
HOLDER: BAD POSITION. AUTO ADJUSTMENT FAILED.	Message reserved to the service people.

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MESSAGE	ACTION
HOLDER: CLOSE DOOR TO ADJUST.	Message reserved to the service people.
HOLDER: CLOSING ERROR	Check if something prevent the door closing.
HOLDER: ERROR WHILE OPENING.	Check if something prevent the door opening.
HOLDER: NO TUBE HOLDER DETECTED.	Put the tube holder.
HOLDER: OPENING ERROR	Check if something prevent the door opening.
ID AND/OR PID MANDATORY (CHECK SETUP). SID ALWAYS MANDATORY.	Enter an ID and/or PID and SID
INIT PRINTER	Switch on the printer or invalidate the printings.
INTERN: COUNT ERROR	Re-start the Mythic.
INTERN: MEMORY CORRUPTED	Re-start the Mythic.
INTERN: NO MEMORY AVAILABLE	Re-start the Mythic.
INTERN: RESULT AREA IS LOCKED	Wait before performing a cycle. If persisting, re-start the Mythic.
INVALID DATA FORMAT.	
LOT ALREADY EXISTS. ACTION CANCELLED.	Select another lot.
LYSE ALMOST EMPTY	Replace the bottle and perform a prime Lysis
MECA: HOME NEEDLE NOT FOUND	Perform an initialization or a control cycle.
MECA: HOME ROCKER NOT FOUND	Perform an initialization or a control cycle.
MECA: HOME SYRINGE NOT FOUND	Perform an initialization or a control cycle.
MECA: MOTOR NEEDLE BUSY	Re-start the Mythic.
MECA: MOTOR NEEDLE GAP	Nothing.
MECA: MOTOR ROCKER BUSY	Re-start the Mythic.
MECA: MOTOR ROCKER GAP	Nothing.
MECA: MOTOR SYRINGE BUSY	Re-start the Mythic.
MECA: MOTOR SYRINGE GAP	Perform a pistons greasing.
MECA: NEEDLE NOT IN TOP POSITION	Perform a control cycle.
NETWARE: SERVER INIT. FAILED	Check your analyzer configuration
NETWARE: CLIENT INIT. FAILED.	Check your analyzer configuration
NO PRINTER RESPONSE	Switch on the printer or invalidate the printings.
NO PRINTER SELECTED	Switch on the printer or invalidate the printings.
NO PRINTER SELECTED	Switch on the printer or invalidate the printings.
NUMBER MAX. OF FILES REACHED. PLEASE DELETE FILES.	Delete data on the selected directory.
OUT OF RANGE	Modify the value
PRINTER DRIVER UPDATE FAILED. THE CHOSEN DRIVER IS NOT COMPATIBLE WITH THE MYTHIC 22 SYSTEM.	Select the right driver compatible with the Mythic.
PRINTER ERROR	Switch on the printer or invalidate the printings.
PRINTER IS BUSY	Switch on the printer or invalidate the printings.
PRINTER IS OFF	Switch on the printer or invalidate the printings.
PRINTER: NO PAPER	Add some paper.
RINSE NOT DONE	Perform a clean cycle.
RS232: ACK ERROR	Re-start the Mythic.
RS232: INTERNAL ERROR	Re-start the Mythic.
RS232: SYNCHRO ERROR	Re-start the Mythic.
RS232: TIME OUT	Re-start the Mythic.
RUNNING AUTO CLEANING	Press OK.
SET TEMPERATURE REACHED.	The instrument is ready to work,
SETUP: MODIFICATION NOT ALLOWED.	You have to be Logged with the good access code.
START UP CYCLE NOT DONE	Perform a start up cycle.
STARTUP CYCLE FAILED	Perform a new start up cycle
SVM: BAD VERSION	Update the SVM software
SVM: COM. TIME OUT	Re-start the SVM.
SVM: ILLEGAL SERIAL NUMBER.	This MYTHIC cannot be connected to the SVM
SVM: UNMATCH	Re-enter the file or confirm it (manual connection on the SVM).
SVM: WG	Westgard alarm.
SVM: XB	XB alarm.
SYSTEM LOCKED HEATING FAILED	Call an Orphée representative.
SYSTEM: DOWNLOADING NEW VERSION. PLEASE WAIT	System is resetting after the version released.
SYSTEM: EEPROM COM ERROR	Re-start the Mythic.
SYSTEM: FATAL ERROR	Re-start the Mythic.

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MESSAGE	ACTION
SYSTEM: INTERNAL TIME OUT	Re-start the Mythic.
TEMPERATURE OUT OF RANGE	Room temperature out of range (<18 or >34°C).
THE CLEANER USED IS OUT OF DATE.	Replace the bottle and perform a prime Cleaner
THE DILUENT USED IS OUT OF DATE.	Replace the container and perform a prime Diluent
THE LYSE USED IS OUT OF DATE.	Replace the bottle and perform a prime Lysis
USB: DIRECTORY DOES NOT EXIST.	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: DIRECTORY IS NOT EMPTY.	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: EMPTY FILE	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: THUMB DRIVE I/O ERROR.	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: THUMB DRIVE IS FULL.	No memory available in USB for storage. You have to delete some data to work.
USB: THUMB DRIVE IS NOT PRESENT.	Connect an USB thumdrive.
USB: TOO MANY FILES OPENED.	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: UNABLE TO CREATE DIRECTORY.	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: UNABLE TO OPEN DIRECTORY.	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: UNABLE TO OPEN FILE	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: WRITE PROTECTED FILE.	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
VERSION RELEASE FAILED. THE CHOSEN RELEASE IS NOT COMPATIBLE WITH THE MYTHIC 22 SYSTEM.	Select the correct version.
WASTE ALMOST FULL	Replace the waste container
USB: DIRECTORY DOES NOT EXIST.	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: DIRECTORY IS NOT EMPTY.	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: EMPTY FILE	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: THUMB DRIVE I/O ERROR.	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: THUMB DRIVE IS FULL.	No memory available in USB for storage. You have to delete some data to work.
USB: THUMB DRIVE IS NOT PRESENT.	Connect an USB thumdrive.
USB: TOO MANY FILES OPENED.	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: UNABLE TO CREATE DIRECTORY.	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: UNABLE TO OPEN DIRECTORY.	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: UNABLE TO OPEN FILE	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
USB: WRITE PROTECTED FILE.	The USB thumdrive as an incompatible tree structure for the analyzer, try another one.
VERSION RELEASE FAILED. THE CHOSEN RELEASE IS NOT COMPATIBLE WITH THE MYTHIC 22 SYSTEM.	Select the right version.
WASTE ALMOST FULL	Replace the waste container

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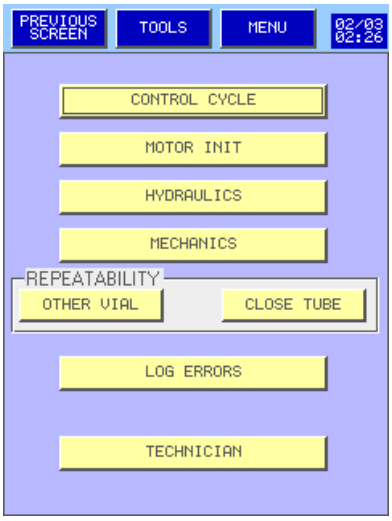
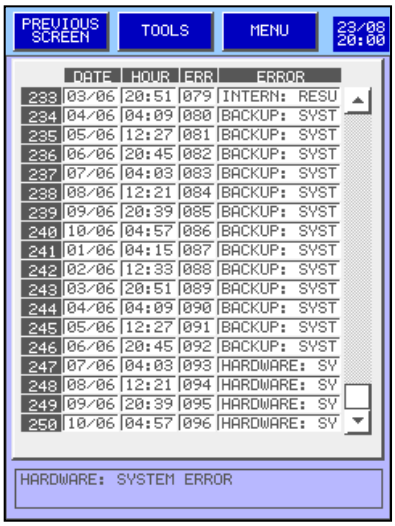
9.7 LOGS ERRORS



- From the MAIN MENU press SERVICE .

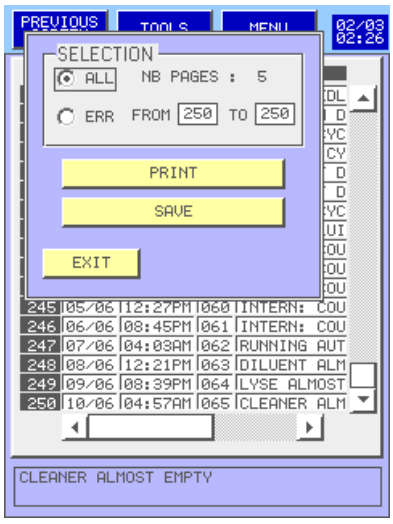
- Then press LOG ERRORS



- This screen allows to visualize the date and time when an error has occurred, as well as the code and the origin of this error.

- To see the origin of the error, press on the figure located on the left of the date, the complete error appears at the bottom.

- To print it press TOOLS .



- Select ALL to print the errors of the number of pages indicated on the screen.

- Select ALL to print the errors of the number of pages indicated on the screen.
- To print or save (in an USB key) the error of one or more days select ERR FROM 250 TO 250 then enter the error reference number.

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9.8 HYDRAULIC DIAGRAM

The length and inner diameters of the tubing shown on the diagram below the tubing table must be strictly respected when replaced, otherwise there is a significant risk in the quality of results given.

	PVC	PU	PVC	PVC	PU	PVC	PVC	PVC	PVC	PVC	SILICON
	0.38 mm	1 x 3 mm	1 x 2.70 mm	1.3 x 3 mm	1.55 x 3.4 mm	1.55 x 3.4 mm	2.1 x 4 mm	2.29 mm	2.79 mm	3.2 x 6.4 mm	2.4x4 mm
Designation											
Tubing 5							210				
Tubing 6							130				
Tubing 8						80					
Tubing 12 - CT					55						
Tubing 13						250					
Tubing 14						250					
Tubing 17						80					
Tubing 18						80					
Tubing 22				200							
Tubing 3							135+20				
Tubing 10 - CT						350					
Tubing 30				130							5
Tubing 31				80							5
Tubing 32						510					
Tubing 33 - CT		300					20				
Tubing 34 - CT						160 + 110					
Tubing 35							130				
Tubing 36							230				
Tubing 37						190					
Tubing 38 - CT							150 + 30				
Tubing 39							180				
Tubing 40						960					
Tubing 41						200					
Tubing 42						180					2 x 5
Tubing 43			250				3 x 15				2 x 5
Tubing 44							270				
Tubing 45							100				
Tubing 46						400					
Tubing 47			240				3 x 15				2 x 5
Tubing 48						150					5
Tubing 49						70					
Tubing 50	100						2 X 20				5
Tubing 51									180		
Tubing 52						50					
Tubing 53						60					
Tubing 54			365								
Tubing 55			140					2 x 15			
Tubing 56						15					
Tubing 58						835 +165			10		
Tubing 59					8						
Tubing 60 - CT							430				
Tubing 61 - CT							240			100	
Tubing 62 - CT							200			100	
Tubing 63 - CT							30				
Tubing 64 - CT						70					
Tubing 65 - CT							60				

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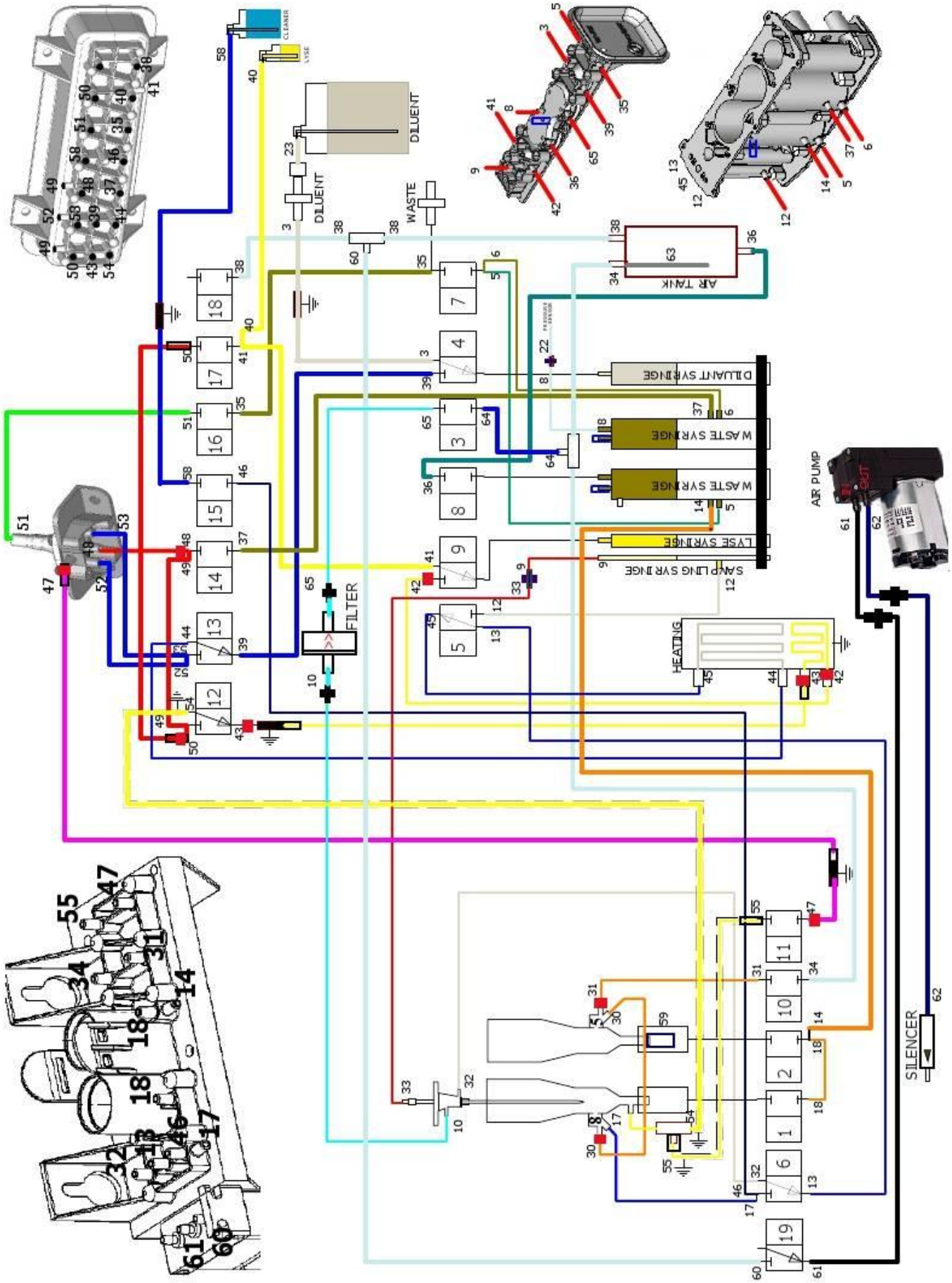

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